

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2021

Findings Date: January 26, 2021

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: E-11987-20

Facility: Blue Ridge Surgery Center

FID #: 170067

County: Burke

Applicants: Blue Ridge HealthCare Hospitals, Inc.

Blue Ridge HealthCare Surgery Center, LLC

Project: Cost overrun for Project ID #E-11298-17 (develop a new ambulatory surgery center by separately licensing four existing operating rooms, two gastrointestinal endoscopy rooms and one procedure room on the Valdese campus)

### REVIEW CRITERIA

G.S. §131E-183(a): The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC (hereinafter referred to collectively as “the applicant”) proposes a cost overrun (COR) for Project I.D. #E-11298-17. That project approved the development of a new ambulatory surgical facility (ASF), Blue Ridge Surgery Center (BRSC), by separately licensing four existing operating rooms (ORs), two existing gastrointestinal endoscopy (GI endo) rooms, and one existing procedure room on the campus of Carolinas HealthCare System Blue Ridge – Valdese (CHS Blue Ridge – Valdese).

A certificate of need was issued on March 12, 2019 for Project I.D. #E-11298-17 and authorized a capital cost of \$1,433,190. The current application proposes a capital cost increase of \$737,540 over the previously approved capital cost for a total combined capital cost of \$2,170,730. The cost overrun application is necessary due to increased costs for construction necessary to comply with building codes and licensure rules. The application proposes no material change in scope from the originally approved project.

### **Need Determination**

There were no need determinations in the 2017 State Medical Facilities Plan (SMFP) applicable to Project I.D. #E-11298-17 and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2020 SMFP. Therefore, there are no need determinations applicable to this review.

### **Policies**

There were no policies in the 2017 SMFP that were applicable to this review. In the current COR application, the combined projected capital cost to develop the project is greater than \$2 million; thus, Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2020 SMFP applies to this review.

Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*, on page 31 of the 2020 SMFP, states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The combined proposed capital expenditure for both projects is greater than \$2 million but less than \$5 million. In Section B, page 11, the applicant states:

*“CHS Blue Ridge is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. The guiding principles followed by CHS Blue Ridge will apply in the development of the proposed project to develop Blue Ridge Surgery Center, a separately licensed, freestanding ASF.*

In Section B, pages 11-12, the applicant outlines its guiding principles, describes the outcomes it hopes to accomplish, and states it is using a design team with experience in Energy Star and with Hospitals for a Healthy Environment Green Guide for HealthCare.

The applicant provides a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The application does not propose any changes to the original proposal that would make any need determinations applicable to this review.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant provides a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

- (2) Repealed effective July 1, 1987.
- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes a COR for Project I.D. #E-11298-17, which approved the development of BRSC, a new ASF on the campus of CHS Blue Ridge - Valdese, by separately licensing four existing ORs, two existing GI endo procedure rooms, and one existing procedure room.

A certificate of need was issued on March 12, 2019 for Project I.D. #E-11298-17 and authorized a capital cost of \$1,433,190. The current application proposes a capital cost increase of \$737,540 over the previously approved capital cost for a total combined capital cost of \$2,170,730. The cost overrun application is necessary due to increased costs for construction necessary to comply with building codes and licensure rules. The application proposes no material change in scope from the originally approved project.

**Patient Origin**

On page 51, the 2020 SMFP defines the service area for ORs as “...*the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” Figure 6.1 on page 57 of the 2020 SMFP shows Burke County as a single county OR service area. The 2017 SMFP identified the same single county OR service area for Project I.D. #E-11298-17.

Neither the 2017 SMFP nor the 2020 SMFP define the service area for GI endo rooms. 10A NCAC 14C .3901(6) defines the service area for GI endo rooms as “...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Project I.D. #E-11298-17, the applicant identified the service area as Burke, Caldwell, McDowell, and Catawba counties.

Thus, the service area for this facility consists of Burke, Caldwell, McDowell, and Catawba counties. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately identified the projected patient origin for the facility. The applicant proposes no changes in the current application which would change the projected patient origin from the previous project, or which would otherwise affect the Agency’s determination in that project.

**Analysis of Need**

The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

<b>BRSC – Previously Approved &amp; Proposed Capital Cost</b>			
	<b>Previously Approved (E-11298-17)</b>	<b>Projected Changes to Capital Cost (E-11987-20)</b>	<b>New Total Projected Capital Cost</b>
Construction/Renovation Contract(s)	\$1,323,190	\$255,384	\$1,578,574
Architect/Engineering Fees	\$110,000	\$14,600	\$124,600
Reimbursables and CON Fees	\$0	\$202,556	\$202,556
Low Voltage Systems	\$0	\$265,000	\$265,000
<b>Total Capital Cost</b>	<b>\$1,433,190</b>	<b>\$737,540</b>	<b>\$2,170,730</b>

In Section C, pages 22-23, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- Increased Construction Contract Costs: In Project I.D. #E-11298-17, the applicant anticipated minimal construction would be needed to develop the proposed project, which involved physically separating existing hospital space into a separately licensed ASF. After the certificate of need was issued, the applicant received confirmation from the Agency’s Construction Section that more construction would be necessary in order to develop the proposed ASF according to building codes and licensure rules. The applicant states the increased costs for construction are due to the additional construction required.
- Increased Architect & Engineering Fees: The applicant states that, due to the design changes necessary to develop the proposed project, the applicant incurred additional costs involving redesigning architectural drawings and schematics.
- Other: The applicant states these fees were not included in the previous application and include costs for asbestos abatement, reimbursables for the design team, electrical testing, fees for the Agency’s Construction Section to review the plans, and contingency costs.
- Low Voltage Systems: The applicant states these fees were not included in the previous application because it was not thought to be necessary to relocate the main OR information technology closet; however, the current architect, in developing designs to comply with building codes and licensure rules, believes the relocation is necessary to meet building codes and requirements.

The information is reasonable and adequately supported based on the following:

- The applicant adequately explains the reasons the additional costs are necessary to develop the proposed project.
- The applicant provides supporting documentation for its statements in Exhibits C.10-1, C.10-2, F.5-1, and K.5-2, including copies of email correspondence with the Agency’s Construction Section and design schematics.
- The applicant does not propose to change the scope of services offered or to change the patients projected to be served by the proposed project.

### Projected Utilization

In Project I.D. #E-11298-17, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. The applicant proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency's determination in that project.

Comments submitted during the public comment period suggest it is not reasonable for the applicant to rely on its previously projected utilization since there have been changes to utilization of certain services since the previous application was approved. The comments suggest the applicant should have revised its projected utilization to account for those changes and because of potential impacts on utilization due to the pandemic.

In Project I.D. #E-11298-17, the Agency found the application conforming to all relevant statutory criteria and a certificate of need was issued to develop a new, separately licensed ASF. In this application, the applicant is not required to demonstrate the need to develop a new, separately licensed ASF a second time. The applicant must demonstrate the need it has for the proposed increase in projected capital costs which exceed 15 percent of the previously approved capital costs. There is nothing in the application as submitted or in the public comments submitted which suggest revised projected utilization calculations are necessary for the applicant to demonstrate the need it has for the proposed increase in projected capital costs to develop the previously approved project.

### Access

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The application for Project I.D. #E-11298-17 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination.
  - The applicant adequately explains why the proposed increase in projected capital cost is necessary to provide the population to be served with the services proposed in this application.
  - Projected utilization was deemed reasonable and adequately supported in Project I.D. #E-11298-17 and there are no changes proposed in this application which would affect that determination.
  - The application for Project I.D. #E-11298-17 adequately identified the extent to which all residents, including underserved groups, were likely to have access to the proposed services, and there are no changes proposed in this application which would affect that determination.
- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

In Project I.D. #E-11298-17, Criterion (3a) was not applicable to that review. There are no changes proposed in this application which would affect that determination. Therefore, Criterion (3a) is not applicable to this review.

- (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.

CA

The applicant proposes a COR for Project I.D. #E-11298-17, which approved the development of BRSC, a new ASF on the campus of CHS Blue Ridge - Valdese, by separately licensing four existing ORs, two existing GI endo procedure rooms, and one existing procedure room.

In Section E, pages 29-30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need.

The applicant states the only other alternative to filing the COR application is to cease development of the previously approved project. The applicant states ceasing to develop the previously approved project would result in higher costs to patients needing outpatient surgery because the charges would be based on receiving hospital-based outpatient surgical services

instead of charges based on surgical services at a freestanding ASF. The applicant further states ceasing development of the previously approved project would no longer allow for physician partnerships and the benefits of those partnerships. For those reasons, the applicant determined ceasing development of the proposed project was not the most effective alternative.

On pages 29-30, the applicant states its proposal is the most effective alternative because it will offer patients lower costs for surgical services performed at a freestanding ASF and it will allow for physician partnership which will attract more physicians to the area.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant does not propose to change the scope of the previously approved Project I.D. #E-11298-17.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC (hereinafter certificate holder) shall materially comply with the representations in this application, the representations in Project I.D. #E-11298-17, and any supplemental responses. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The total combined capital expenditure for both projects is \$2,170,730, an increase of \$737,540 over the capital expenditure of \$1,433,190 previously approved in Project I.D. #E-11298-17.**



- 3. The certificate holder shall develop a new ambulatory surgical facility. Blue Ridge Surgery Center, by relocating four operating rooms, two gastrointestinal endoscopy rooms, and one procedure room from CHS Blue Ridge – Valdese.**
- 4. Upon completion of the project and Project I.D. #E-11298-17, Blue Ridge Surgery Center shall be licensed for no more than four operating rooms, two gastrointestinal endoscopy rooms, and one procedure room.**
- 5. Upon completion of the project and Project I.D. E-11298-17, the certificate holder shall take the necessary steps to delicense four operating rooms, two gastrointestinal endoscopy rooms, and one procedure room from CHS Blue Ridge – Valdese such that CHS Blue Ridge – Valdese will no longer be licensed for any operating rooms or gastrointestinal endoscopy rooms.**
- 6. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on May 1, 2021. The second progress report shall be due on August 1, 2021 and so forth.**
- 7. The certificate holder shall not acquire as part of this project any equipment that is not included in this project's and Project I.D. #E-11298-17's combined proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 8. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 9. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in this application, in Project I.D. #E-11298-17, and in any supplemental responses without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**

- 10. The procedure room shall not be used for procedures that should be performed only in a gastrointestinal endoscopy room or for procedures that should be performed only in an operating room based on current standards of practice.**
  - 11. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in a gastrointestinal endoscopy room or operating room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room or operating room.**
  - 12. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  - 13. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. Payor mix for the services authorized in this certificate of need.**
    - b. Utilization of the services authorized in this certificate of need.**
    - c. Revenues and operating costs for the services authorized in this certificate of need.**
    - d. Average gross revenue per unit of service.**
    - e. Average net revenue per unit of service.**
    - f. Average operating cost per unit of service.**
  - 14. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (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.

## C

The applicant proposes a COR for Project I.D. #E-11298-17, which approved the development of BRSC, a new ASF on the campus of CHS Blue Ridge - Valdese, by separately licensing four existing ORs, two existing GI endo procedure rooms, and one existing procedure room.

### **Capital and Working Capital Costs**

The applicant projects the total capital cost to develop BRSC (as approved in Project I.D. #E-11298-17) will be \$2,170,730, an increase of \$737,540 over the previously approved capital expenditure. The total proposed capital cost is 151 percent of the previously approved capital expenditure and thus requires a certificate of need. The following table compares the

previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

<b>BRSC – Previously Approved &amp; Proposed Capital Cost</b>			
	<b>Previously Approved (E-11298-17)</b>	<b>Projected Changes to Capital Cost (E-11987-20)</b>	<b>New Total Projected Capital Cost</b>
Construction/Renovation Contract(s)	\$1,323,190	\$255,384	\$1,578,574
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Reimbursables and CON Fees	\$0	\$202,556	\$202,556
Low Voltage Systems	\$0	\$265,000	\$265,000
<b>Total Capital Cost</b>	<b>\$1,433,190</b>	<b>\$737,540</b>	<b>\$2,170,730</b>

In Project I.D. #E-11298-17, the Agency determined the applicant had demonstrated the projected capital cost was based on reasonable and adequately supported assumptions. There are no changes proposed in this application which would affect that determination.

In Section C, pages 22-23, the applicant explains the need for the proposed increase in projected capital costs. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

On Form F.1b in Section Q, the applicant provides the assumptions used to project the proposed increase in capital cost. The applicant adequately demonstrates that the proposed increase in the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant had previously demonstrated to the Agency in Project I.D. #E-11298-17 that the projected capital costs in that application were based on reasonable and adequately supported assumptions, and there are no changes proposed in this application which would affect that determination.
- The applicant explains the need for the different costs that make up the combined total increase in capital cost for this COR application and the explanations are reasonable and adequately supported.
- The applicant provides supporting documentation for the need for the proposed capital cost increase and the assumptions regarding the proposed capital cost increase in Exhibits C.10-1, C.10-2, and F.5-1.

In Project I.D. #E-11298-17, the applicant did not propose any start-up costs or initial operating expenses. The Agency determined Project I.D. #E-11298-17 was conforming to this criterion. In Section F, page 36, the applicant states there are still no projected start-up costs and initial operating expenses.

### **Availability of Funds**

In Project I.D. #E-11298-17, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$1,433,190. The current application proposes a capital cost increase of \$737,540 over the previously approved capital cost for a combined total capital cost of \$2,170,730.

In Section F, pages 36-37, the applicant states the increase in projected capital costs will be funded through the accumulated reserves of Blue Ridge HealthCare Hospitals, Inc.

Exhibit F.5-2 contains a letter dated October 15, 2020 from the president and CEO of Blue Ridge HealthCare Hospitals, Inc. and the manager of Blue Ridge HealthCare Surgery Center, LLC, stating Blue Ridge HealthCare Hospitals, Inc. will provide the funding for the projected increase in capital costs from accumulated reserves.

Exhibit F.5-3 contains the Consolidated Financial Statements for the Blue Ridge HealthCare System, Inc., the parent company of the applicant, for the years ending December 31, 2019 and 2018. As of December 31, 2019, Blue Ridge HealthCare System, Inc. had adequate cash and assets to fund the proposed increase in the projected capital cost.

The applicant adequately demonstrates the availability of sufficient funds for the proposed increase in the projected capital cost based on the following:

- The applicant provides a letter from an appropriate company officer confirming the availability of the funding proposed for the capital needs of the project and a commitment to use that funding accordingly.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

### **Financial Feasibility**

In Project I.D. #E-11298-17, the applicant projected revenues would exceed operating expenses during each of the first three full fiscal years of operation following project completion. The Agency determined Project I.D. #E-11298-17 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges. The applicant projects no changes in this application to those projections and no changes which would otherwise affect the Agency's previous determination.

Comments submitted during the public comment period suggest the financial feasibility of the previously approved project is questionable because the applicant did not provide any updated pro formas reflecting any increases in leasing costs due to the increased projected capital cost. In supplemental information requested by the Agency, the applicant states the proposed increase in projected capital cost will be incurred by the applicants but there will be no increase in operating costs or fees as a result of the proposed increase in projected capital cost. In Section F, page 36, the applicant further states:

*“The previously approved application included operating costs for a lease; thus, the separately licensed ASF did not project to incur costs associated with depreciation. This assumption is unchanged with the projected increase in capital costs in the proposed project, and no other revenue or operating costs are impacted by the proposed cost overrun project.”*

The applicant’s explanation is reasonable and adequately supported; the comments submitted during the public comment period provide no other information to change that analysis.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the increased capital cost is based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the increased capital cost of the proposal for all the reasons described above.
  - The applicant projects no changes to the assumptions and methodology in Project I.D. #E-11298-17 which demonstrated projected capital costs were reasonable and adequately supported and which adequately demonstrated the availability of sufficient funds for the capital costs.
  - The applicant projects no changes to the assumptions and methodology in Project I.D. #E-11298-17 which demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal was based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes a COR for Project I.D. #E-11298-17, which approved the development of BRSC, a new ASF on the campus of CHS Blue Ridge - Valdese, by separately licensing four existing ORs, two existing GI endo procedure rooms, and one existing procedure room.

On page 51, the 2020 SMFP defines the service area for ORs as “...*the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” Figure 6.1 on page 57 of the 2020 SMFP shows Burke County as a single county OR service area. The 2017 SMFP identified the same single county OR service area for Project I.D. #E-11298-17.

Neither the 2017 SMFP nor the 2020 SMFP define the service area for GI endo rooms. 10A NCAC 14C .3901(6) defines the service area for GI endo rooms as “...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Project I.D. #E-11298-17, the applicant identified the service area as Burke, Caldwell, McDowell, and Catawba counties.

Thus, the service area for this facility consists of Burke, Caldwell, McDowell, and Catawba counties. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrate that the project would not result in unnecessary duplication of existing or approved services in the service area. The applicant proposes no changes in the current application which would affect the Agency’s determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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.

### C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated the availability of sufficient health manpower and management personnel to provide the proposed services. The applicant proposes no changes in the current application which would affect the Agency’s determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the all the reasons stated above.

- (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.

C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the

project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (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.

C

The applicant proposes a COR for Project I.D. #E-11298-17, which approved the development of BRSC, a new ASF on the campus of CHS Blue Ridge - Valdese, by separately licensing four existing ORs, two existing GI endo procedure rooms, and one existing procedure room.

A certificate of need was issued on March 12, 2019 for Project I.D. #E-11298-17 and authorized a capital cost of \$1,433,190. The current application proposes a capital cost increase of \$737,540 over the previously approved capital cost for a total combined capital cost of \$2,170,730. The cost overrun application is necessary due to increased costs for construction and other expenses necessary to comply with building codes. The application proposes no material change in scope from the originally approved project.

The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.



<b>BRSC – Previously Approved &amp; Proposed Capital Cost</b>			
	<b>Previously Approved (E-11298-17)</b>	<b>Projected Changes to Capital Cost (E-11987-20)</b>	<b>New Total Projected Capital Cost</b>
Construction/Renovation Contract(s)	\$1,323,190	\$255,384	\$1,578,574
Architect/Engineering Fees	\$110,000	\$14,600	\$124,600
Reimbursables and CON Fees	\$0	\$202,556	\$202,556
Low Voltage Systems	\$0	\$265,000	\$265,000
<b>Total Capital Cost</b>	<b>\$1,433,190</b>	<b>\$737,540</b>	<b>\$2,170,730</b>

In Project I.D. #E-11298-17, the Agency determined this criterion was not applicable to that review. Due to the proposed increase in the projected capital cost and design changes necessary to meet applicable building codes and licensure rules, this criterion is applicable to the present review.

In Project I.D. #E-11298-17, the applicant stated the separately licensed ASF would occupy 29,360 square feet of existing space and involve renovations to 400 square feet and provided line drawings. In supplemental information requested by the Agency, the applicant states:

*“...there is no change whatsoever to the scope of the project. The project involves the conversion of an existing hospital-based surgical facility to a separately licensed, freestanding ASC. The cost overrun application is necessitated only by an increase in construction costs. The square footage and location of the ASC within the existing building has not changed.”*

The applicant provides updated line drawings in Exhibit K.5-2 and correspondence with the Agency’s Construction Section about requirements for meeting the appropriate building codes and licensure rules in Exhibits C.10-1 and C.10-2.

In Section C, pages 22-23, and Section E, page 30, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant identifies the changes necessary due to requirements for building codes and licensure rules, explains them in detail, and provides supporting documentation in Exhibits C.10-1 and C-10.2.
- The applicant states that the conversion of existing space into a freestanding ASF will result in cost-effectiveness for patients already being served by CHS Blue Ridge – Valdese.

In Section F, pages 36, and in supplemental information requested by the Agency, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- In Section F, page 36, the applicant states that the proposed increase in projected capital cost will not impact projected revenue or operating costs approved in Project I.D. #E-11298-17.
- In supplemental information requested by the Agency, the applicant further states there will be no changes to the lease rate or to any other projected revenue or operating costs approved in Project I.D. #E-11298-17.

In Section B, pages 11-12, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Comments submitted during the written comment period suggest the application is nonconforming to Criterion (12) because it does not provide certain documentation of requirements imposed by the Agency's Construction Section and provides responses from the Agency's Construction Section regarding architectural plans submitted for review but does not provide the applicant's response to those responses from the Agency's Construction Section.

One of the responses from the Agency's Construction Section is dated October 10, 2020; the application deadline for this review was October 15, 2020. It is not reasonable to expect the applicant to draft responses to those comments from the Agency's Construction Section, submit them, and do so in enough time to include that response in the application submitted five days later.

However, even if it was reasonable, the Project Analyst does not have the statutory authority to require the applicant to provide responses to the Agency's Construction Section. G.S. 131E-175 through 131E-190 contain no language that would allow the Project Analyst to require any applicant to provide responses related to other administrative rules or other North Carolina statutes. Please see the Working Papers for additional information.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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 ... persons [with disabilities], 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;

C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated 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. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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

In Project I.D. #E-11298-17, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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

C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated the elderly and the medically underserved groups identified in this subdivision would be served by the applicant's proposed services and the extent to which each of these groups would be expected to utilize the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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.

C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this 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.

C

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (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.

C

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On page 51, the 2020 SMFP defines the service area for ORs as “...*the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” Figure 6.1 on page 57 of the 2020 SMFP shows Burke County as a

single county OR service area. The 2017 SMFP identified the same single county OR service area for Project I.D. #E-11298-17.

Neither the 2017 SMFP nor the 2020 SMFP define the service area for GI endo rooms. 10A NCAC 14C .3901(6) defines the service area for GI endo rooms as “...*the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Project I.D. #E-11298-17, the applicant identified the service area as Burke, Caldwell, McDowell, and Catawba counties.

Thus, the service area for this facility consists of Burke, Caldwell, McDowell, and Catawba counties. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #E-11298-17, the Agency determined the applicant had adequately demonstrated the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition would have a positive impact upon the cost effectiveness, quality, and access to the services proposed. The applicant proposes no changes in the current application which would affect the Agency’s determination in that project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

On Form A in Section Q, the applicant identifies the facilities with ORs and/or GI endo rooms located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies one such facility located in North Carolina. However, the applicant is part of a joint venture with Atrium Health which makes Atrium Health a related entity. Atrium Health owns, operates, or manages 20 additional facilities with ORs and/or GI endo procedure rooms in North Carolina.

In Section O, page 54, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred

at the facility identified by the applicant in Form A. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there was one incident related to quality of care at one of the 21 facilities; that facility is back in compliance as of the date of these findings. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 21 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

In Project I.D. #E-11298-17, the Agency determined the application was conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, which were in effect at that time. The applicant proposes no changes in this application which would affect that determination. Additionally, on December 1, 2018, the Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 were amended, and the amended rules are not applicable to either the current COR proposal or the previously approved Project I.D. #E-11298-17.

Project I.D. #E-11298-17 did not reference the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Healthcare Facilities, promulgated in 10A NCAC 14C .3900. However, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Healthcare Facilities were not applicable to that review. That rule has not been amended and remains in effect at the time of this decision; this application does not propose any changes that would make the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Healthcare Facilities applicable to this review.

Therefore, there are no Criteria and Standards applicable to this review.