Comments on Caldwell Surgery Center

submitted by

Carolinas HealthCare System - Blue Ridge

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Carolinas HealthCare System - Blue Ridge (CHSBR) submits the following comments related to an application to develop a new ambulatory surgery center. CHSBR's comments include *"discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, CHSBR has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following application:

- **Caldwell Surgery Center (CSC), Project ID # E-10358-14**

GENERAL COMMENTS

CHSBR notes that this application proposes the same project as the application for Project ID # E-10261-14, which was disapproved by the Agency on August 28, 2014. Although the application that is currently under review will be reviewed on its own merit, and while the current application has some differences from the first application, CHSBR believes that the differences, including attempts to repair some issues cited in the Agency Findings on the first application, are insufficient to cure the significant deficiencies that persist. These comments will address issues in the current application, but will also note issues present in the first, denied application that remain in the current application. Where relevant, CHSBR incorporates by reference its written comments filed in opposition to Project ID # E-10261-14. In fact, it should be noted that there are multiple issues for which the previous denied application was found non-conforming that are also present in this application and have not been corrected. As such, this application should also be denied.

As with the previous application, while CHSBR understands that freestanding ambulatory surgery centers (ASCs) can offer certain advantages over hospitals in terms of lower costs and charges in some instances, the application contains multiple fatal flaws and should not be approved. Given the similarities of scope, size, location and specialties between the current and previous applications, it is helpful to note the differences, particularly as they relate to issues with which the

previous application was found non-conforming. Perhaps the most glaring and substantive difference is in the utilization projections and support from physicians. Compared to the previous disapproved application, the physician letters of support project fewer surgical cases, yet the application projects higher utilization of the proposed ASC's operating rooms. The table below shows the differences.

Factor	*March 2014 Application*	*October 2014 Application*
Surgical Volume in Support Letters	3,745 to 4,910	3,130 to 3,780
Projected Surgical Utilization (ASC)	3,661	3,864

Incredibly, *even with fewer surgical cases projected in its letters of support*, and even in light of the denial of its previous application, CSC *has projected even higher surgical volume* in the current application. Although the letters of support are just one part of its need analysis, multiple other issues exist that also render CSC's utilization projections unreasonable, as discussed in further detail below.

In addition, although multiple comments and the Agency Findings for the previous denied application discussed this issue, CSC has once again completely failed to demonstrate the need for the proposed project at the proposed location in the southeastern corner of Caldwell County. The Findings from the previous application point out that numerous factors that CSC used in its application to attempt to demonstrate need provided no rationale or correlation between the need argument and the proposed location of the ASC. For instance, the lack of a freestanding ambulatory surgery center in the county, or the growth in ambulatory surgical cases as a national trend, or the lower reimbursement structure for freestanding ASCs do not explain the reason for the proposed development of an ASC with three ORs and one procedure room at the location proposed by CSC. Even after its denial in the previous application, CSC continues to fail to explain a correlation between its need arguments and the proposed project. This is demonstrated most clearly starting on page 70 of the application, where CSC makes numerous statements regarding correlations—without actually explaining any correlation. For example, the application states that there is a correlation between the higher median age of county residents (compared to the state) and an unmet need for the proposed ASC near the southern county line. ***Yet, the applicants never explain the correlation, beyond merely asserting that there is one.*** It is clear that the applicants completely miss the point—that none of the demographic or statistical factors they present have any bearing on the scope or location of their project, but could equally support multiple types of surgical projects. In fact, as demonstrated below, it is clear that the proposed project will actually be located away from the most at-risk or

medically underserved population in the county. Therefore, this application, like the previous application, should be denied on the same basis, as well as others discussed below.

Further, as with the previous denied application, this application fails to demonstrate its ability to recapture patients currently leaving the county, as residents are currently predominantly choosing to receive outpatient surgery for non-eye cases at hospitals rather than ASCs. Moreover, the largest volume of patients leaving the county for ambulatory surgery are going to Greystone Surgery Center, which provides ophthalmologic surgery, a specialty CSC does not propose to offer. CSC even points out the fact that the number of cases being performed on Caldwell residents in ASCs increased from 2012 to 2013, ignoring the fact that the greatest increase was to ASCs with specialties not supported by any physician letters, including ophthalmology and ENT.

APPLICATION-SPECIFIC COMMENTS

CSC's application should not be approved as proposed. CHSBR identified the following specific issues, each of which contributes to CSC's non-conformity:

(1) Failure to demonstrate that the proposed project is the least costly or most effective alternative;
(2) Unsupported and unreasonable financial assumptions;
(3) Understated capital costs and lack of documentation of available funds;
(4) Failure to demonstrate the need for the proposed project; and,
(5) Failure to demonstrate that the proposed ASC will be a multi-specialty ambulatory surgery program.

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, CHSBR has identified the statutory review criteria creating the non-conformity.

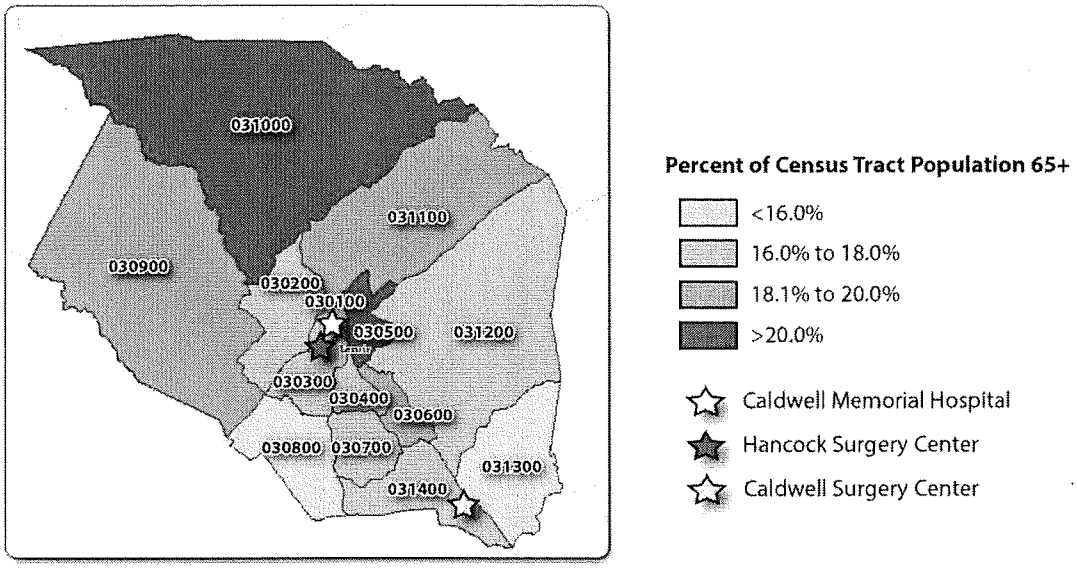
Failure to Demonstrate that the Proposed Project is the Least Costly or Most Effective Alternative

CHSBR believes that CSC has failed to demonstrate that the proposed project is the least costly or most effective alternative. Specifically, CSC proposes to move operating room capacity from the center of Caldwell County to the southeastern corner of the county. This location is simply not as convenient for the majority of Caldwell County residents. A central location would be more effective at reducing the outmigration of Caldwell County residents to facilities in other

counties, a central goal of the proposed project. Additionally, other healthcare services are available in the central part of the county, whereas the proposed ASC appears to be one of the first healthcare facilities proposed for that area. Although the application lists several alternatives considered by the applicants, it does not indicate that it considered a location in the central part of the county. The applicants do address issues raised in comments on the previous denied application regarding the conversion of Hancock Surgery Center; however, it fails to justify or sufficiently explain the rationale for the chosen location compared to a more central location in the county. The applicants point to the percentage of county residents that live in the southeastern part of the county; however, they fail to document that those residents are the ones currently seeking care at CMH or its surgery center (and therefore part of the shift of cases from CMH) or if they are part of the expected market share gains, nor do they explain why a more central location would not provide access to that population as well as the rest of the county. This analysis is important for two reasons. First, the application fails to demonstrate that the relocation of ORs to the southeastern corner of the county would not create a geographic barrier for residents in the central or western parts of the county. The applicants have access to their own surgical patient origin data by ZIP code; thus, they should be able to identify what part of the county their patients (and thus their current market share) are from. Second, the application fails to demonstrate that the residents of the southeastern corner of the county have a need for the proposed project that is similar to or even greater than the county as a whole. This is particularly important for medically underserved patients, including those over 65, the poor and indigent, women and minorities. As shown in the following maps, based on 2014 data from Claritas[1], the location proposed by CSC is generally farther from these groups than a more central location within the county.

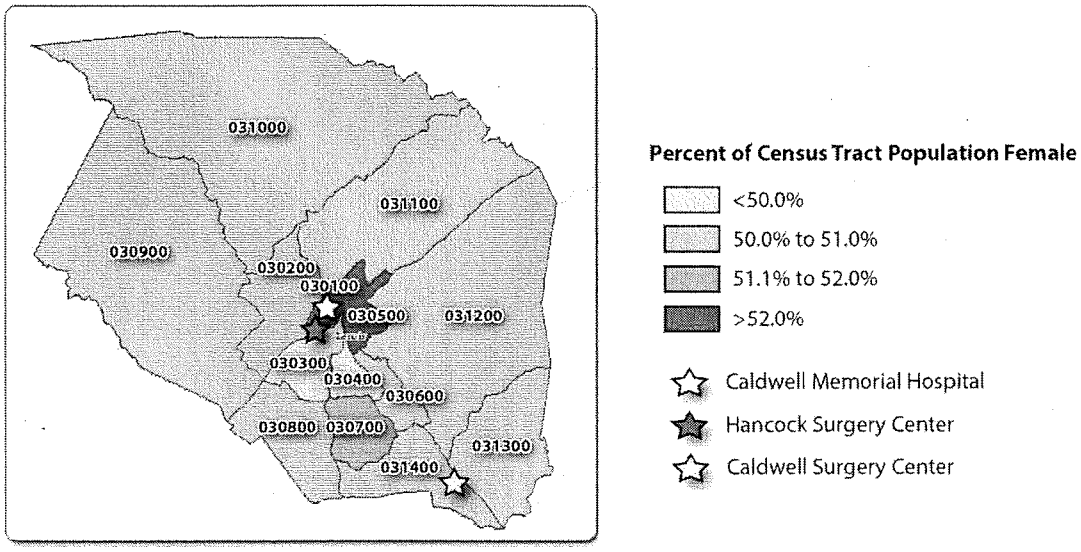
The first map shows the population of the county that is 65 and older by census tract.

[1] Claritas provides data by census tract, while the Office of State Budget and Management does not. Some census tracts were combined by Claritas.



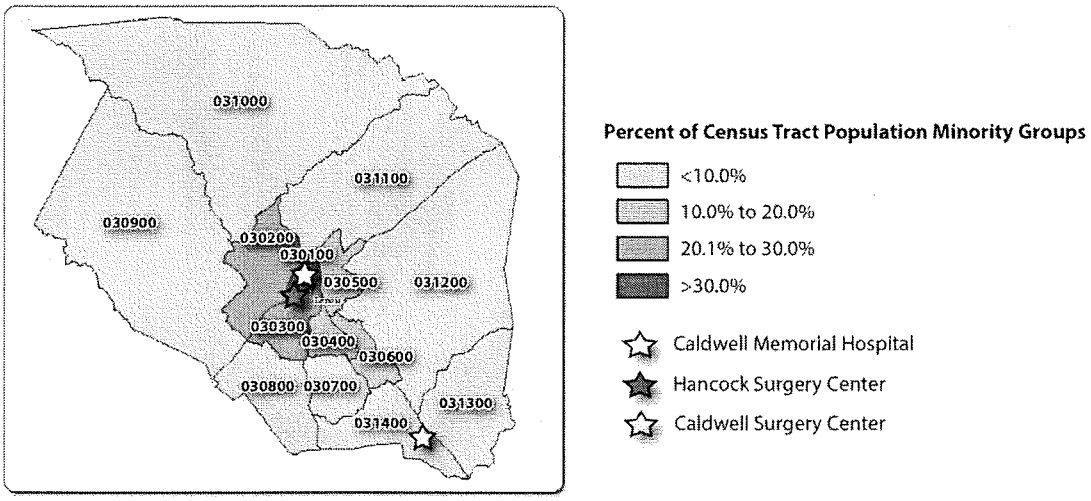
As shown, the area of the county with a higher percentage of older population—those in greatest need of healthcare services such as surgery—is the central and western portion of the county.

The next map shows the population of the county that is female.



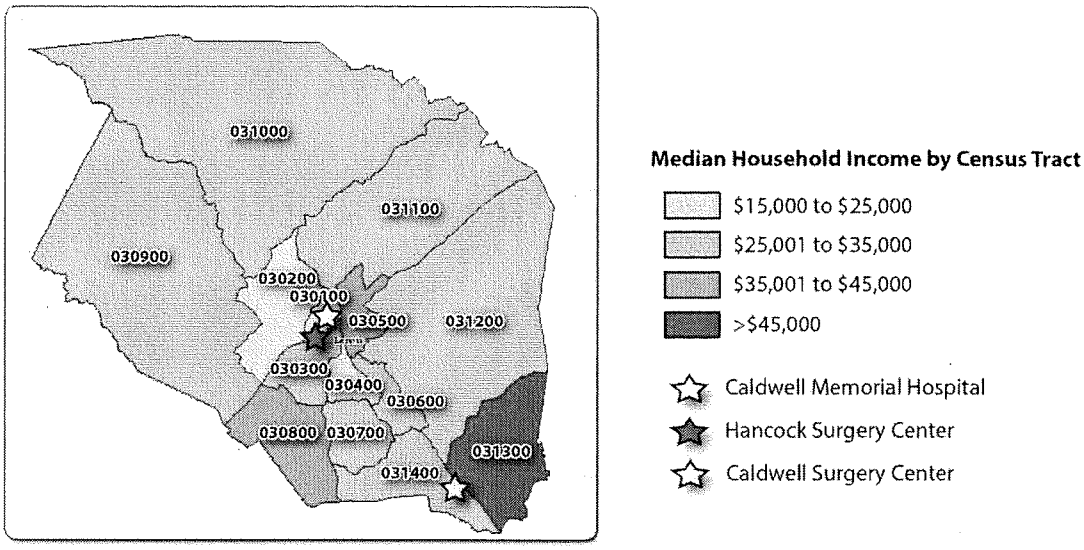
Although most of the census tracts are fairly even between genders (around 50 percent male/female), the tracts in the center of the county show a higher concentration of women compared to most of the rest of the county.

The next map shows the minority population of the county.



Clearly, the concentration of minority groups is in the center of the county, and the proposed relocation of ORs to CSC would put them farther away from this medically underserved population.

The final map shows the household income in the county.



As shown, the central part of the county is clearly the poorest, with the census tracts with median household incomes between $15,000 and $25,000, which would indicate poverty for most average sized families. Conversely, the tract with the highest median income is located near the proposed site for CSC.

These facts are relevant to the review of this application for several reasons. First, as discussed above, CSC has not demonstrated how its location will enhance access to these medically underserved groups, compared with another location, particularly the central part of the county. Second, several statutory review criteria require an applicant to demonstrate the impact of its project on these medically underserved groups, and it is clear that the proposed relocation will be farther away from the greatest number of medically underserved. Third, the CON Section has previously determined that a similar proposal was non-conforming with several review criteria because of the relocation of existing services away from the medically underserved, notwithstanding the proposed relocation to a more populated area of the county. See Agency Findings for Project ID #K-8024-07. Fourth, these are the groups of people that are likely to have the greatest need for the proposed project. That is, the enhanced access that the applicants assert will result from the development of a freestanding ASC would be expected to benefit those in need of surgery (which is more frequently the older population, such as those 65 and older) and those with lower incomes, including the poor and indigent. While some patients might be willing to travel for care, those at greatest risk, including patients who are older and/or indigent, often have difficulty accessing services at a distance from their homes. Since CSC is proposing to move away from the areas where those populations are

highest, it has failed to demonstrate that its proposed would be the most effective location for meeting the needs of this population.

Given these facts, CSC has failed to demonstrate the proposed project is the least costly or most effective alternative, or that it is needed by the population it proposes to serve. **Based on these issues, the application should be found non-conforming with Criteria 3, 3a, 4 and 13(c), as well as the applicable regulatory criteria.**

Unsupported and Unreasonable Financial Assumptions

CSC's financial projections include incorrect and unsupported financial assumptions; as a result, the financial feasibility of the proposed project is not demonstrated by the application. The management agreement for the facility as shown in Exhibit 5 states on page 63 that the management fee will be *"equal to twelve (12) percent of net revenue or $109,545 per month in Year 1, inflated at a rate of four* percent." The proforma financial statements on page 132 calculate the management fee based on 12 percent of net revenue, which is lower than the annual fee at $109,545 per month. The following table demonstrates the understatement of management fees in each of the three project years:

Impact of Understated Management Fees

Year	*PY1*	*PY2*	*PY3*
As shown in Financials (12% of Net Revenue)	$1,149,084	$1,195,047	$1,242,849
Based on $109,545 per month, inflated four percent annually	$1,314,540	$1,367,122	$1,421,806
Understatement of Management Fees	**$165,456**	**$172,075**	**$178,957**

CSC's understatement of its management fees also indicates that it has understated its initial operating expenses, as an increased amount of expenses will be incurred during the initial operating period. Given this understatement of expenses, CSC has not demonstrated that is has access to sufficient funds to cover its total start-up and initial operating expenses. CSC made the same error in the previous denied application; in responsive comments filed at the public hearing, it indicated that the $109,545 was a "typographical error" from a management contract for another facility. Given that more than six months passed between the first application and this application, it seems unlikely that the applicants would not have had time to correct a typographical error,

particularly given that they were given notice in comments filed in the previous review.

CSC's financial statements include no support for its projected reimbursement, including the rates for each procedure, the number of procedures per case, or the projected average reimbursement for operating room and procedure room cases. Exhibit 20, which is also reproduced on page 144 of the application, shows projected reimbursement by procedure. At the bottom of the page, CSC provides its assumption for *"Average Reimbursement for Surgery Cases Performed in Procedure Room."* However, CSC does not provide any source for this information or statement on how these reimbursement figures were derived that could be used to assess their validity. Moreover, near the bottom of the table, CSC calculates *"Weighted Average of CSC Reimbursement per Procedure."* Given its placement in the table, it appears as though this weighted average is based only on the Top 20 procedures to be performed at the facility rather than all of the procedures to be performed at the facility. If so, this may result in an overstatement of the average reimbursement for operating room cases, which would impact the financial feasibility of the proposed project. Finally, CSC calculates *"Reimbursement Per Surgery Case (OR Cases Only)"* by multiplying the *"Weighted Average of CSC Reimbursement per Procedure"* by 1.6 procedures per case. CSC provides no justification for the 1.6 procedures per case figure. Absent any information about this statistic, the financial feasibility of the project cannot be adequately demonstrated.

On page 105 of the application, CSC states that "[t]*he proposed project is expected to have a similar payor mix as the historical patient percentages for ambulatory surgery at the hospital because CSC and its physicians are committed to provide high levels of access to the medically underserved population of Caldwell County.*" This assumption is identical to the assumption provided in the previous denied application, and it is once again simply unreasonable given the differences between the surgical specialties offered at the CMH and projected to be performed at CSC and the differences in the geographic locations of the two facilities and the demographics of the surrounding communities. As stated explicitly in the application on page 65 and assumed in the projected procedures to be performed in the facility as shown in the financial statements, CSC is assumed to provide Orthopedic & Spine, Podiatry, and General Surgery and Vascular cases only. Although the application also includes urology, ENT and other, as explained below, it is clear that the top 20 procedures and financials do not include these types of cases. By contrast, CMH provides these specialties as well as Obstetrics and GYN, Otolaryngology, and Endoscopy on an outpatient surgery basis, as shown in its 2014 Hospital License Renewal Application. Given the difference in service mix between the two facilities, it is unreasonable to assume that the payor mix will be equivalent. For example, otolaryngology patients tend to be, on average, younger and more likely to be on Medicaid. The absence of that service line from CSC's

facility would thus result in a fewer Medicaid patients on average. The Agency Findings in the previous denied application found the application non-conforming with Criterion 13(c) on this basis; given the identical assumption and lack of reasonable support, the Agency should find this application non-conforming as well.

Moreover, the proposed CSC will be located in a community that is younger and more affluent than CMH's community as explained above. This is also demonstrated by a direct comparison of the ZIP codes for the hospital and the proposed ASC. CSC will be located in ZIP code 28630 per page 2 and CMH is located in ZIP code 28645 [please note that the application (like the previous denied application) contains numerous typographical errors, which erroneously state that the hospital is located in ZIP code 28745]. According to the 2010 U.S. Census data summarized in the table below, CSC's ZIP code has a lower percentage of age 65 and over, a lower median age, and a higher median household income than CMH's ZIP code.

Comparison of CSC and CMH ZIP Codes

	CMH ZIP Code 28645	*CSC ZIP Code 28630*
Percent of Population 65 and Over	17%	13%
Median Age	42.1	39.9
Median Household Income	$32,036	$43,797

Source: U.S. Census Bureau, 2010 Census Data.

Communities with more individuals aged 65 and older are likely to have more Medicare patients. Communities with higher incomes are likely to have a higher percentage of Commercial/Managed Care patients and fewer Medicaid, uninsured, poor and indigent patients. Given these differences in the surrounding communities, it is unlikely that two facilities with identical service offerings would have the exact same payor mix, never mind two facilities which have substantially different services. Thus, CSC's payor mix is based on unreasonable assumptions.

Given these factors, CSC should be found non-conforming with Criteria 5 and 13(c).

Understated Capital Costs and Lack of Documentation of Available Funds

As with the previous denied application, this application does not include sufficient capital costs, nor does it demonstrate the availability of funding for the requisite capital costs. Even if the applicants are not responsible for the cost of

the building construction, the building is an essential part of the ASC, and is part of the development of the new institutional health service – the ambulatory surgical facility.

The applicants make several statements on page 114 regarding the exclusion of the building costs that are either incorrect or irrelevant, as follows:

- "*The lessor of the space will incur no capital costs for the development of the institutional [sic] health service of this project.*"

  This statement is incorrect. The definition of "new institutional health service" in NCGS § 131E-176(16)(a) includes "the construction, development of other establishment of a new health service facility." The definition of "health service facility" in (9b) of the same section includes an ambulatory surgical facility. Thus, the development of the proposed ambulatory surgical facility, including its construction, is part of the new institutional health service, and the capital costs for the construction of the facility should be included.

- "*Representatives of [the applicants] confirmed with CON officials that the owner/lessor of the building space was not required to be a CON co-applicant because SCSV, LLC will incur all of the capital costs related to the proposed CON project.*"

  The latter portion of the statement is incorrect, as explained in the previous point. The lessor will, indeed, incur substantial capital costs related to the development of the CON project and without which the new institutional health service (the ambulatory surgical facility) could not be developed. The former portion of the statement is therefore irrelevant. Moreover, the issue is not whether the lessor needs to be a co-applicant, but whether the lessor's costs need to be included. Even if the lessor will not operate the service, it will incur capital costs in the development of an ambulatory surgical facility, which, as noted above, is a new institutional health service.

Based on the construction cost estimate in Exhibit 38, which was developed at the request of CMH, one of the applicants, it is clear that more than $8.1 million in necessary costs were omitted from the capital costs in Section VIII. The applicants have failed to consider that the development of the building to house the ASC is an essential part of the new institutional health service. The building that will house the ASC is not a physician office building, as it will house only the ASC, a regulated health service facility.

Because the building will clearly be used solely for development of the new ambulatory surgical facility, which is a new institutional health service, any certificate of need must include the cost of the building. Moreover, the building will clearly be used only to develop a health service facility, the ASC. As such, NCGS 131E-176(16)(b) applies, as the cost to develop the health service facility well exceeds $2 million.

Even if there were other services being provided in the building, such as physician offices, in other CON applications in which only a portion of a building was being used to house a new institutional health service, applicants provided all costs associated with the development of that portion of the space to be used for the new institutional health service, irrespective of who was developing it. This approach is in keeping with the requirements of the CON Act that all necessary costs be accounted for in an application.

As a result of the failure to include necessary capital costs and funding, the application should be found non-conforming with Criterion 5.

Failure to Demonstrate the Need for the Proposed Project

Expansion of Outpatient Services at Valdese Hospital

CSC attempts to bolster its need arguments by implying that changes at the Valdese campus of Carolinas HealthCare System - Blue Ridge support the need for its project. It is quite clear from publically-available documents that the opposite is true. Not only does the Valdese campus have some of the most modern, state-of-the-art surgical suites in the region, but the transition of the campus to an outpatient destination is expected to increase, not decrease, the level and volume of ambulatory services available there, including surgery. As noted in the press release from June 25, 2014 available on CHSBR's website, the transition will begin with the relocation of inpatients to Morganton and the increase of "outpatient surgeries performed at Valdese[2]." This fact was reaffirmed more recently in another press release that discussed the transition of the Valdese campus[3]. Thus, the changes at Valdese, particularly the relocation of inpatient surgery to Morganton, will bolster the capacity for and availability of ambulatory surgery in the region. This fact relates directly to the proposed project, since Valdese is closer to the location of the proposed facility. According to www.google.com/maps, the proposed ASC in Granite Falls, in the southeastern corner of Caldwell County, would be closer to the CHSBR Valdese campus than

---

2 http://www.blueridgehealth.org/news/Blue-Ridge-to-Transform-Valdese-Campus.pdf

3 http://www.blueridgehealth.org/Valdese-Hospital-Continues-Transformation-to-Outpatient-Health-Center.pdf

to Caldwell Memorial Hospital (CMH). Specifically, the proposed site is approximately 14.8 miles from CMH, but only 12.8 miles from the Valdese campus. CSC's failure to account for these changes, particularly given that it acknowledged its awareness of the changes at the Valdese campus, notwithstanding its failure to adequately avail itself of publically available information.

Ambulatory Surgery Use Rates for Caldwell County

CSC states that the need for the proposed project, and, accordingly its ability to achieve the projected market share, is driven by the lack of access to freestanding ambulatory surgery center services in Caldwell County. However, the data provided in the application does not support that position. On page 41 of this application, CSC provides data which shows that the vast majority of patients who leave Caldwell County for ambulatory surgery services seek care at hospitals, not ASCs. In fact, of the 1,989 Caldwell County residents that sought care at an ASC, 63 percent went to Greystone Surgery Center, a single specialty ophthalmological ASC. CSC will not provide ophthalmology surgery and thus cannot serve the highest number of patients leaving the county for freestanding ASC services. Given the fact that most Caldwell County patients who leave the county seek outpatient surgery at hospitals, it is likely that most are doing so as a result of physician referral relationships and patient preference. CSC's application does not provide a reasonable basis to support its ability to change such patterns; therefore, the market share assumptions and need for the proposed project has not been demonstrated.

Moreover, Caldwell County's ambulatory surgery use rate, as shown on page 53, is 33 percent higher than the North Carolina use rate. In addition, the use rate grew from 2012 to 2013, even without access to a freestanding ASC within Caldwell County. As such, Caldwell County residents do not appear to have an issue with regard to accessing outpatient surgery services and they have historically chosen to access those services in hospital settings. In its decision in the 2003 MRI Planning Area 15 Review, the Agency stated that a comparison of use rates can indicate access to services, in that case, for MRI services:

> *Accessibility to MRI services may also be assessed by a comparison of MRI utilization rates. Counties with higher MRI use rates (i.e., number of county residents who received MRI services per 1,000 population) may reflect higher access to MRI services, and counties with lower MRI use rates may reflect less access to MRI services. The following table shows the total number of residents who received MRI procedures during 2002 by county, and the MRI use rate per 1,000 population.*

COUNTY OF ORIGIN	MRI PATIENTS (1)	2002 POPULATION (2)	MRI USE RATE PER 1,000 POPULATION
Randolph	5,473	133,836	40.89
Davidson	6,233	150,799	41.33
Rockingham	6,565	92,589	70.90
Guilford	31,462	428,794	73.37

(1) Based on MRI patient origin data reported to the Division of Facility Services for 2002.
(2) North Carolina State Office of Demographics population estimates by county for July 2002.

As indicated by the table above, Randolph County and Davidson County had the lowest MRI use rates of all of the counties in MRI Service Area 15.

See pages 56-57 of the Agency Findings.

Unreasonable Market Share Assumptions

In an effort to demonstrate the need for the proposed project, CSC has made unreasonable assumptions including projecting to achieve in excess of 100 percent market share of specific outpatient service lines in Caldwell County. On page 44 of its application, CSC states that it uses *"market share assumptions of 38% in Year 1, 42.0% in Year 2 and 46.0% in Year 3."* These are the same market share assumptions used in the previous denied application, notwithstanding the fact that the market share for other providers has increased (page 41) and the projected cases in the physician letters of support have decreased. In addition, these market share assumptions are simply impossible given that CSC projects to provide only Orthopedic & Spine, Podiatry, General Surgery and Vascular cases. According to databases compiled by the Medical Facilities Planning Section from the 2014 License Renewal Applications, Orthopedic, General Surgery, Vascular, and Podiatry cases account for at most 43.6 percent of total outpatient surgical cases in North Carolina in 2013.

North Carolina Outpatient Surgery by Specialty

Specialty	*Hospitals*	*Freestanding ASCs*	*Total*	*% of Total*
Orthopedics*	106,697	38,340	145,037	22.5%
Ophthalmology	72,327	65,220	137,547	21.3%
General Surgery	111,483	8,945	120,428	18.6%
ENT	40,790	28,068	68,858	10.7%
OBGYN	52,059	5,221	57,280	8.9%
Urology	35,072	2,939	38,011	5.9%
Plastic Surgery	14,946	2,812	17,758	2.7%
Neurosurgery	10,959	1,547	12,506	1.9%
Other-Not Podiatry^	14,788	1,726	16,514	2.6%
Oral Surgery	11,582	1,357	12,939	2.0%
Podiatry^	2,354	5,262	7,616	1.2%
Vascular	8,348	296	8,644	1.3%
Cardiothoracic	2,738	0	2,738	0.4%
Total	484,143	161,733	645,876	100.0%
Subtotal for CSC Specialties	**228,882**	**52,843**	**281,725**	**43.6%**

*Spine cases are assumed to be included in the Orthopedic service line consistent with CMH's License Renewal Application.

^Podiatry is not separately identified on the License Renewal Application form as a specialty area. However, many facilities, including CMH, record their Podiatry cases in one of two Other categories on the form and note that the Other category includes Podiatry. In order to be as conservative as possible, CHSBR included all cases in both Other categories where Podiatry is recorded by the facility on the License Renewal form. In many instances, Podiatry is listed alongside other specialties and so the Other cases include specialties types beyond Podiatry. Those surgical cases recorded in the two Other categories where Podiatry was not listed are including the Other-Not Podiatry specialty in the table above.

Source: Medical Facilities Planning Section Databases for Hospitals and Ambulatory Surgery Centers, compiled from 2014 License Renewal Applications.

Assuming that outpatient surgical volume in Caldwell County has a service mix similar to the rest of the state, the specialties proposed by CSC account for, at most, 43.6 percent of total outpatient surgery volumes in the county. Therefore, it is simply unreasonable and impossible for CSC to achieve 46 percent market share of total outpatient surgery for the county, as only 43.6 percent of the total cases in the county are for surgical services that CSC will provide[4]. In fact, CSC has assumed that it will achieve 106 percent market share of Orthopedic, General Surgery, Vascular, and Podiatry cases in the county, as shown in the table below.

---

4 CHSBR notes that in the previous denied application, CSC also projected to achieve 46 percent market share, but the specialties it projected totaled a slightly higher percentage of the total, 43.8%. Thus, as unreasonable as its projections were in the previous application, they are even more incredible in this application, given the updated data.

	Year 3
Projected Ambulatory Surgery Cases for Caldwell Population (see page 57)	7,499
Percent of Total Ambulatory Surgery Cases in CSC Specialties	43.6%
Projected Ambulatory Surgery Cases for Caldwell Population in CSC Specialties	3,270
Projected Caldwell Surgery Center Cases in Caldwell County (see page 57)	3,450
CSC Effective Market Share of CSC Specialties in Caldwell County	**106.0%**

It should again be noted that this is an even higher market share than projected in the previous denied application. Although CSC essentially admits on page 57 that the specialties for which it has support letters are insufficient to support its projected utilization, it cites to its recruitment and marketing plans to bolster its projections, as well as its "open access policies." While CSC may at some point in the future recruit additional physicians, such a goal is insufficient to support quantitative utilization projections, and as a UNC-owned facility, it should be aware of this fact. Another UNC-owned facility, Rex Hospital, made similar arguments in 2010 regarding utilization projections made by Novant Health in its proposal to develop a three-OR ASC in Wake County. In the contested case hearing that followed that review, Administrative Law Judge Donald W. Overby determined in his Recommended Decision (10 DHR 5724 and 5275) that the application for the Novant facility (Holly Springs Surgery Center, or HSSC) did not conform with Criterion 3. The recommended decision states that *"Mr. Carter [the expert for Rex] noted that the number of cases represented by the three specialty types for which HSSC did obtain physician support letters - orthopedic surgery, general surgery, and neurosurgery- is insufficient to result in a 60% market share by project year three in the Holly Springs census tract, as projected by HSSC"* (Findings of Fact #78, page 24). In that instance, HSSC's projections resulted in an effective market share above 100 percent in a single census tract; by contrast, CSC projections show an effective market share of over 100 percent in an entire county, Caldwell County, and are therefore even more unreasonable.

CSC's market share assumptions are unreasonable and unachievable on their face. CSC does make statements in its application that it expects to recruit additional surgeons in the future to practice at CSC; however, it is by no means certain or guaranteed that those surgeons will choose to practice at the ASC. The mere development of an ASC at which surgeons may practice in no way guarantees that a particular surgeon will choose to do so. CSC's assumptions are even more speculative considering that the proposed ASC would essentially be the first medical facility in the area. The applicants have failed to describe other medical facilities around which this facility might be developed, such as physician offices. Unlike other healthcare services, such as urgent care, the physician--the surgeon--is essential to the provision of the service. In other

words, patients may choose an urgent care facility based on its proximity alone; however, they cannot do the same for surgery. The surgeon must be willing and able to perform the surgery him- or herself. Without the presence of local offices for the surgeons to see patients, surgeons may be unwilling to travel to the proposed ASC, and absent commitments to do so, such assumptions are mere speculation.

Although CSC asserts that it will recruit surgeons in additional specialties that may practice at the proposed ASC, such statements do not correlate with the rest of the application. In particular, the following portions of the application do not indicate any relation to the performance of ENT or urology cases at the ASC:

- The top 20 procedures list does not include any ENT or urology cases (page 144 and Exhibit 20);
- The letters of support from physicians include none from otolaryngologists or urologists;
- The projected utilization and mix of cases is stated to be based on physician estimates (page 131); thus, with no support from surgeons to perform ENT or urology cases, the projected cases appear to exclude ENT and urology;
- The assumed recruitment is purported to take place over a multi-year period (see letter from Vice President of Business Development in Exhibit 23), yet the applicants make no corresponding changes in assumptions regarding case type or volume over the three year period;
- The financial statements do not appear to include any ENT or urology volume.

Unreasonable Methodology

The methodology presented by the applicants is unreasonable, for several reasons. For simplicity, CHSBR has provided comments for each step of the methodology, which begins on page 55.

Step 1 shows a one-year increase in ambulatory use rates for Caldwell County, which the applicants imply should be expected to continue. However, it is unclear that the one-year timeframe is indicative of a trend. Although the Caldwell County health director's letter of support indicates her belief that use rates will increase, there is no evidence that she has any experience, knowledge or expertise in planning for healthcare services, including ambulatory surgery. Moreover, the analysis of ambulatory use rates is not part of one of the 10 Essential Public Health Services and no analysis is presented in the letter; thus, the statement by the health director is merely conjecture.

Step 2 assumes a 0.75 percent increase in ambulatory surgical use rates through 2019. Other than the one-year experience presented in the previous step, no other analysis is shown to demonstrate the reasonableness of this assumption. The applicants state that technological changes and changes in reimbursement have increased the demand for ambulatory surgery; however, given that these changes have already occurred, it is unclear how they will cause the growth in use rates in the future. In addition, as stated above, the applicants fail to explain how any such increase in use rates, even if it were to occur, necessitate the development of the proposed facility in the youngest and wealthiest part of the county.

Step 3 assumes market share gains, which are unsupported as described in detail above. It should also be noted, however, that even if the applicants are successful in recruiting surgeons in additional specialties, and even if those surgeons practice at the proposed facility, it is still unreasonable to assume such market share gains, given that one or two surgeons in a particular specialty are unlikely to be able to perform all the surgery required by county residents in that specialty. In other words, the applicants fail to demonstrate that the successful recruitment of one urologist will enable them to capture all or a significant portion of the urology surgery cases currently being performed elsewhere.

Step 4 assumes that patients from other counties will inmigrate to the proposed ASC. As with the previous denied application, the issue with this assumption is that the proposed facility will be farther from the existing, centrally-located facilities in Lenoir. As such, it is not reasonable to expect the same or a similar (14 percent versus 12 percent) percentage of patients to travel further for care, particularly when, in the case of Watauga and Wilkes counties, other options are available.

Step 5 projects the specific percentage of patient origin for each county from which the applicants expect to receive patients. Other than stating that the percentages were adjusted for the expected increase of patients from Caldwell County, the applicants fail to provide any rationale by which the percentages were calculated. Therefore, the assumptions are unsupported.

Step 6 calculates the need for operating rooms; however, since it is based on the preceding steps, which are unreasonable, the applicants have failed to demonstrate the need for the proposed number of operating rooms.

Step 7 projects shifts of cases from CMH to the proposed ASC, as well as projected market share for CMH. The applicants project, without a reasonable basis, both the inpatient and outpatient market share at CMH to increase through the third project year. While the applicants state that the increase in inpatient

cases is based on the aging of the population and physician recruitment, the population also aged between 2012 and 2014, yet inpatient cases decreased substantially, as shown on page 64. Further, the applicants use physician recruitment to support its ambulatory surgical projections for CSC. It is unclear and unexplained why it is reasonable to expect an increase in ambulatory surgery cases due to technology and reimbursement changes, along with the newly recruited surgeons, while also stating that the inpatient cases will increase, notwithstanding the projected shift of inpatient cases to the outpatient setting. Also missing from this application is a discussion of how patients currently receiving care at the Hancock Surgery Center will be cared for following the relocation of the ORs to the proposed ASC. In particular, as noted in Caldwell Memorial Hospital's 2014 Hospital License Renewal Application, Hancock Surgery Center provides Obstetrics and GYN as well as Otolaryngology surgical services, neither of which is projected to be performed at CSC. CSC's utilization methodology, top 20 procedures, physician support, extant medical staff, and financial statements all assume that the facility will only provide Orthopedic & Spine, Podiatry, and General Surgery and Vascular cases. Thus, the applicants have failed to explain how or where patients from other specialties will receive care.

Step 8 is based on the applicants' market share assumptions, which as addressed above, are unreasonable. Therefore, the outcome of step 8 is also unreasonable.

Step 9 projects the mix of surgical cases by type. The applicants state that the assumptions are based on the medical staff, support letters and "conservative" estimates for the physicians that are expected to be recruited. However, an examination of the projections shows that these assumptions are not reasonable. First, the applicants project a total of 464 podiatric cases in Year 3. The support letters do include two podiatrists; however, their total number of projected cases is between 350 and 400, and the applicants indicate no plans to recruit additional podiatrists. Thus, it is unclear how the applicants derived either the 12 percent of total cases or the total of 464, and the text under the table on page 65 indicates that the assumption is 15 percent, not 12. It is also unclear what amount of the 38 percent assumed for general surgery, vascular, urology, ENT and other is for general and vascular surgery, which are the only two specialties (vascular as a sub-specialty of general) for which there is support.

As a result of these issues, the application should be found non-conforming with Criteria 3 and 3a, as well as the applicable regulatory criteria.

Failure to Demonstrate that the Proposed ASC will be a Multi-specialty Ambulatory Surgery Program

As defined by 131E-176(15a), a "'[m]*ultispecialty ambulatory surgical program' means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.*" CSC proposes to provide only two of the above listed specialties, general surgery and orthopedic, according to its utilization methodology, top 20 procedures, physician support, extant medical staff, and financial statements. Based on its own representations, CSC will not provide at least three of the specialty areas as required by the General Statute.

As such, CSC must not be approved as a multispecialty ASC and even if approved and developed must apply for a CON to add specialties in the future.

SUMMARY

As described in detail above, CSC's application should be found non-conforming with the statutory review criteria and applicable regulatory criteria based on the numerous and substantial issues with its application.