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, Project ID # E-11054-15**

GENERAL COMMENTS

CHSBR notes that this application proposes the same project as two previous applications submitted by Caldwell Memorial Hospital ("CMH") and SCSV, LLC (collectively "CSC") to develop a freestanding ambulatory surgery center ("ASC"): Project ID # E-10261-14, which was disapproved by the Agency on August 28, 2014 and Project ID # E-10358-14, which was withdrawn during its review period. It appears that the current application attempts to correct some of the areas of non-conformity found by the Agency in the first application; however, CHSBR believes that the primary issues in the first application that led to its non-conformity remain, while additional areas of non-conformity have been created in the current application. All of these issues are addressed in these comments, but CHSBR believes the Agency should also refer to comments on the previous two applications and the Agency Findings from Project ID # E-10261-14 (the "Agency Findings"). CHSBR incorporates its relevant comments on the first two applications by reference, and requests that the Agency refer to those comments as well. Given the presence of issues that led to the first denial as well as the additional issues noted below, CHSBR believes that CSC's current application should also be denied.

APPLICATION-SPECIFIC COMMENTS

Unreasonable Location

The current application proposes to locate the project in the same location in southeastern Caldwell County near the Catawba County border as what was proposed in the prior two applications. Yet, this application, like the two previous applications, fails to demonstrate that the project is needed at the proposed location.

The point made in the Agency Findings and comments from multiple parties concerning the prior applications regarding the location is that the application proposes to move three existing operating rooms from Lenoir, which is in the geographic center of Caldwell County, to a location on the far border of Caldwell County—near the Catawba County line. In attempting to address this issue, which was one of the bases of non-conformity with the first application, the application includes letters of support from physicians, some of which state that the Granite Falls location is more convenient for ***those physicians*** than a location in Lenoir. However, neither the application nor the physician letters demonstrate that the proposed location on the far border of the county would be more convenient for the population to be served by the project – the residents of Caldwell County whom the applicant contends need a freestanding ASC located ***within*** the county. Instead, the application contains only a conclusory statement that the proposed location will be "convenient" because an asserted 51 percent of the total Caldwell County population lives in the southeastern region of the county. However, the application does not specify how or why the proposed location would be more convenient. For example, the application does not demonstrate that the distance or travel time to reach surgical services for those residents, particularly residents living in Saw Mills, Hudson, or southern Lenoir, would be reduced if traveling to the proposed location rather than one farther into the county or even the Hancock Surgery Center. Also lacking is any indication that a location other than the existing Hancock Surgery Center or the proposed location near the county line has been considered, such as a location not on the county border that would be closer to more of the population. In fact, the utilization projections demonstrate that even CSC projects that its existing surgeons who practice in Lenoir will serve *fewer* Caldwell County patients once the ASC opens, as discussed in detail below. This fact evinces the application's tacit acceptance of the negative impact of the proposed project on a significant portion of the county's population.

Regardless of whether Lenoir is the population center of the county (as argued in the application), the proposed location is clearly less accessible to the residents of Caldwell County as a whole than a location farther into the center of Caldwell

County. The proposed location is beside the Caldwell-Catawba County line and far from residents living in other parts of the county, especially the roughly 49 percent of the residents who do not live in the southeastern portion of the county. Even for residents who do live in the southeastern section of Caldwell County, the proposed location is not necessarily more convenient or accessible. Very few homes, businesses, and other destinations exist between the proposed location and the Caldwell-Catawba County line, and practically speaking there is little to no effective difference between the convenience offered by a freestanding ASC located at the proposed location and one located on the other side of the county line, such as Viewmont Surgery Center. A location farther within Caldwell County would enhance accessibility for a greater number of Caldwell County residents. Even assuming that that the Caldwell County line ended just beyond the northern/western borders of Lenoir and the half of the county on that side of Lenoir did not exist, the proposed location would still be almost as far away from the population as it can be, given its closeness to the Catawba County border. Most notably, the map on page 43 of the application shows that a more effective location would be close to the actual population center of the county—which, as indicated by the red star, is clearly ***within the municipality of Lenoir***.

The map in Attachment 1 shows block groups within a six mile radius from the proposed location of CSC and the existing location of Hancock Surgery Center. Assuming conservatively that the entire population of each of the block groups that have any portion within the six-mile radius of CSC is closer to the proposed CSC location than to Hancock, the Caldwell County population closer to CSC is approximately one-half the population closer to Hancock. The table in Attachment 2 shows the population demographics for the block groups closer to CSC and those closer to Hancock. Clearly, more of the Caldwell County population is closer to the existing location in Lenoir than to the proposed location for CSC in Granite Falls. In addition, as addressed in the Agency Findings on the first application and the comments on the first two applications, the application proposes to relocate the operating rooms away from areas with higher amounts of medically underserved patients to an area with lower amounts of medically underserved patients. These data are also provided in the table in Attachment 2. The application fails to provide any information that would disprove this fact. This issue is important not only because of the way the Agency has historically analyzed similar projects, but also from a practical perspective. Specifically, the application discusses the desire to expand access to freestanding surgical services to Caldwell County residents within their home county. Given the proposed location and its proximity to existing capacity in Catawba County, the project will not markedly improve access to surgical services. In particular, the proposed location is only five miles from Viewmont Surgery Center in Hickory, a freestanding, multispecialty ASC.

Moreover, as discussed in detail below, the majority of patients served by physicians that would shift their cases from facilities in Burke and Catawba counties are not residents of Caldwell County. This fact provides further evidence that the proposed location is not effective at expanding access for Caldwell residents, as the application states.

As such, the application fails to demonstrate the project is needed in the proposed location, and the application should be found non-conforming with Criteria 3 and 6.

Failure to Properly Identify the Population to be Served

The application includes physician support letters, most of which provide the patient origin for the patients they serve. Many of the letters also specify that only a portion of their total surgical volume would shift to the proposed ASC, and then identifies the percentage of those cases that would represent Caldwell County patients. The patient origin projections in the application are stated to be based on the information in the physician letters; however, they are based on the patient origin for the physicians' total cases, not the specific cases the physicians project to perform at the ASC. The patient origin projections on pages 89-90 of the application also fail to account for the different percentage of Caldwell County patients represented by those more specific case projections. As a result the projected patient origin does not match the projected cases for the ASC. The table below shows the physician letters that do not match the patient origin projections.

Physician	Caldwell County % based on Cases Appropriate to Shift to CSC (from Physician Letters)	Caldwell County Patient Origin as shown in Application (Pages 89-90)
Jenkins	50.0%	74.9%
Keverline	90.0%	94.2%
Stanislaw	90.0%	57.6%
Purcell	70.0%	39.8%
Pantiel	50.0%	70.0%
Hannibal	80.0%	64.9%
Zook	52.0%	5.5%
Geissele	31.0%	9.0%

As a result of these errors, the application has identified a population to be served by county that does not match the utilization projections from the physician letters, which are also used to project utilization in the application.

Therefore, the application should be found non-conforming with Criterion 3.

Failure to Demonstrate Need for the Proposed Project

The application presents the project as a way to develop a freestanding ASC that will expand access to surgical services for Caldwell County residents. Throughout the application, Caldwell County is presented clearly as the focus of the proposed project, and the applicant repeatedly justifies the project on the grounds that Caldwell County does not have and "needs" a freestanding ASC and that the southeastern portion of the county has a particular need for greater access to surgical services. The support letters discuss the access to be provided for Caldwell County patients. The need section of the application presents several reasons that the applicants believe the proposed project is needed, all of which focus on the need of the Caldwell County population. However, the application projects that **the majority of patients served by the proposed project will be from counties other than Caldwell**. As shown in the following table, the patient origin projections for the ASC clearly demonstrate that less than 50 percent of the total patients served will come from Caldwell County.

	Surgery Cases	*Procedures*	*Total*	*Percentage*
Caldwell County	1,514	250	1,764	48.1%
Others	1,501	400	1,901	51.9%
Total	**3,015**	**650**	**3,665**	**100.0%**

Source: Application pages 123 and 124

This is a marked departure from the projections in the previous two applications, which projected the vast majority of patients at the ASC to come from Caldwell County. While the change to reflect the majority of patients coming from outside Caldwell County is more plausible, it does not support the need for a three-operating room ASC to serve Caldwell County patients, which is ostensibly the reason for the project.

Among the other counties from which patients are projected, Catawba and Burke comprise the largest number of patients. Not only is this expected due to the proposed location of the ASC, it also speaks to the issue with the location on the county border as well—located where it will serve more patients from other counties than from Caldwell County. The physician letters from surgeons not currently practicing at CMH also point to this issue, by stating that the Granite Falls location is more convenient for them than a location in Lenoir. These surgeons who do not currently practice in Caldwell County primarily serve patients from counties other than Caldwell (principally Burke and Catawba). This is also a major inconsistency in the application—if the goal is to avoid

outmigration and the proposed ASC is needed to stop outmigration, then why is it reasonable to project an increase in outmigration from other counties (Catawba and Burke) to Caldwell County? The "need" for the ASC on the border of Caldwell County is clearly to attract patients from other counties—not Caldwell—including Catawba County patients, who currently have access to a multispecialty, freestanding ASC in their county. Since less than one-half of the projected patients are projected to be from Caldwell County, the application fails to demonstrate the need for a three-operating room ASC to serve Caldwell patients. In other words, the quantitative "need" for the ASC demonstrates, at best and assuming for the sake of argument that the projections are reasonable, that Caldwell residents need 1.5 operating rooms at the proposed location, not three.

This is particularly problematic given the excess capacity of operating rooms that already exists in Burke and Catawba counties. As shown in the table below, both counties together have a current and projected surplus of more than 20 operating rooms in the *Proposed 2016 SMFP*.

County	*2014 Total Estimated Hours*	*2014-2018 Growth Factor*	*2018 Projected Surgical Hours*	*Standard Hours per OR*	*Projected ORs Needed in 2018*	*Adjusted Planning Inventory*	*Projected OR Deficit or Surplus*
Burke	12,683	0.00%	12,683	1,872	6.77	11	-4.23
Catawba	40,259	0.90%	40,621	1,872	21.70	38	-16.30

In project year three (2020), CSC projects that surgeons who have historically performed cases in existing licensed operating rooms in Burke and Catawba counties will shift a total of 1,110 cases to the ASC. Using 1.5 hours per outpatient case, those cases equates to a total of 1,665 hours. With 1,872 hours as the planning threshold for an operating room, CSC projects to shift 89 percent of that threshold (1,665 ÷ 1,872 = 88.9%), or essentially enough volume to fill one operating room. Thus, rather than simply increasing the utilization of operating rooms in Caldwell County, CSC is projecting to shift the underutilization of the Caldwell County operating rooms to Burke and Catawba counties, where patients are already being served. The application provides no justification of the need for an ASC in Caldwell County to serve patients from Burke and Catawba, nor does it provide any evidence that patients are willing and able to shift from where they are currently being served to the proposed ASC. Since the patients are already being served, particularly the non-Caldwell patients, the application fails to demonstrate any need that these patients have to leave their counties for care. The application will unnecessarily duplicate existing health service facilities in Burke and Catawba counties.

The fact that the proposed project will unnecessarily duplicate existing resources is actually documented in the application. On page 45, the first bullet states that "[a]fter relocation of ORs to CSC, **sufficient OR capacity will remain in the City of Lenoir to accommodate the inpatient and outpatient surgical needs of the entire population of Caldwell County** as well as to accommodate patient in-migration from surrounding areas." (emphasis added) The application contends, therefore, that the three operating rooms to be relocated to Granite Falls to develop CSC are not needed to serve the population of Caldwell County. The only way that the three operating rooms in the ASC can be better utilized is by shifting patients from other counties into Caldwell County for care. These patients are already being served by existing facilities in their home and nearby counties.

For these reasons, the application should be found non-conforming with Criteria 3 and 6.

Utilization Projections Fail to Demonstrate Need for the Project

As another issue, the application projects that the proposed project will actually negatively impact the number of Caldwell County patients being served at CMH and CSC. On page 72 of the application, the applicant states that "Caldwell Surgery Center is expected to reverse the historical trend of high outmigration for the ambulatory surgery patients. The project will increase availability of more surgical specialists within the County…." The following analysis describes why this statement is unfounded.

As shown on page 126 of the application, 87.5 percent of CMH's projected ambulatory surgery patients are projected to be Caldwell County residents. Page 127 states that "the patient origin for CMH is not projected to change in future years." The following table shows the projected CMH cases for Caldwell County residents based on this assumption.

	FY 2014	FY 2015	CY 2016	CY 2017	PY 1	PY 2	PY 3
Total CMH Cases (page 139)	2,876	3,216	3,458	3,724	1,867	1,950	2,036
% Caldwell County (page 126)	87.48%	87.48%	87.48%	87.48%	87.48%	87.48%	87.48%
Total CMH Caldwell County Cases	**2,516**	**2,813**	**3,025**	**3,258**	**1,633**	**1,706**	**1,781**

CSC projects 50.2 percent of its patients to be Caldwell County residents (page 91). The following table shows the projected CSC cases for Caldwell County residents based on this assumption.

	FY 2014	FY 2015	CY 2016	CY 2017	PY 1	PY 2	PY 3
Total CSC Cases (page 140)	-	-	-	-	3,015	3,377	3,740
% Caldwell County (page 91)	-	-	-	-	50.20%	50.20%	50.20%
Total CSC Caldwell County Cases	**-**	**-**	**-**	**-**	**1,514**	**1,695**	**1,877**

As described on page 84, the CSC projections are based on letters from physician who currently perform surgery and endoscopy cases at CMH and Hancock Surgery Center, additional recruited surgeons, and surgeons with practice locations near CSC. As shown in Exhibit 8, 12 of the 18 physicians projected to perform cases at CSC already have privileges at CMH. The remaining six have privileges at facilities in other counties. Based on the projected surgical cases by physician shown on page 86 of the application and the facility privileges shown in Exhibit 8, the following tables shows the projected CSC cases for Caldwell County residents that will be shifted from CMH and Hancock, along with those that will be incremental.

Physician	*Current Facility*	*Total PY 1 Cases*	*Total PY 2 Cases*	*Total PY 3 Cases*
Bast	Caldwell Memorial	280	320	360
Jenkins	Caldwell Memorial	300	300	300
Keverline	Caldwell Memorial	250	275	300
Pezzi	Caldwell Memorial	240	270	300
Stanislaw	Caldwell Memorial	300	300	300
Purcell	Caldwell Memorial	200	225	250
Jaggers	Caldwell Memorial	50	145	240
Hershman	Caldwell Memorial	175	175	175
Pantiel	Caldwell Memorial	150	150	150
Young	Caldwell Memorial	50	75	100
Hannibal	Caldwell Memorial	70	75	80
Nenow	Caldwell Memorial	50	63	75
Zook	Blue Ridge	100	125	150
O'Brien	Catawba	150	175	200
Maxy	Catawba, Blue Ridge	100	125	150
Johnson	Frye, Catawba	300	300	300
Norcross	Frye, Catawba	150	175	200

Geissele	Frye, Catawba	100	105	110
Total		**3,015**	**3,378**	**3,740**
Total Shift from CMH to CSC		**2,115**	**2,373**	**2,630**
Total Incremental to CSC		**900**	**1,005**	**1,110**
CSC % Caldwell County		50.2%	50.2%	50.2%
Caldwell County Shift from CMH to CSC		1,062	1,191	1,320
Caldwell County Incremental to CSC		452	505	557

The table below summarizes the projected Caldwell County patients that will be served at CMH and CSC by existing surgeons—before the addition of any incremental cases from surgeons shifting Caldwell cases from facilities in other counties.

	FY 2014	FY 2015	CY 2016	CY 2017	PY 1	PY 2	PY 3
Total CMH Caldwell County Cases	2,516	2,813	3,025	3,258	1,633	1,706	1,781
Shift of Caldwell County Cases from CMH to CSC	-	-	-	-	1,062	1,191	1,320
Total CMH and Shifted Cases	-	-	-	-	**2,695**	**2,897**	**3,101**
Change from Prior Year	**NA**	**11.8%**	**7.5%**	**7.7%**	**-17.3%**	**7.5%**	**7.0%**

As shown, the application projects that the number of Caldwell County patients served at CMH facilities will increase substantially prior to the development of the project, ***then actually decrease by 17 percent once CSC opens in 2018***. Even by 2020, the third year of the project, the application projects the total number of Caldwell County residents served by existing surgeons to decrease from 3,258 in 2017 to 3,101. Thus, the application projects that the proposed project will not meet its stated objective—and that it will actually drive more Caldwell patients to other providers. The only actual increase in the number of Caldwell County patients served at CMH and CSC will thus come from the additional surgeons who will shift cases from other facilities in Burke and Catawba counties, as shown in the table below.

	FY 2014	FY 2015	CY 2016	CY 2017	PY 1	PY 2	PY 3
Total CMH Caldwell	2,516	2,813	3,025	3,258	1,633	1,706	1,781

County Cases							
Shift of Caldwell County Cases from CMH to CSC	-	-	-	-	1,062	1,191	1,320
Total CMH and Shifted Cases	-	-	-	-	**2,695**	**2,897**	**3,101**
Incremental Caldwell County Cases to CSC	-	-	-	-	452	505	557
Total Caldwell County Cases	**-**	**-**	**-**	**-**	**3,147**	**3,402**	**3,658**
Incremental Caldwell Cases Compared to 2017	**-**	**-**	**-**	**-**	**-111**	**144**	**400**

Given the lack of a demonstration that these additional surgeons will be privileged at CMH, the large number of non-Caldwell patients that they project to shift from counties with excess surgical capacity, and the small incremental increase in cases performed on Caldwell patients (after a decline), the utilization projections do not demonstrate the need for the proposed project.

Based on this analysis, the application should be found non-conforming with Criterion 3.

Unreasonable Utilization Assumptions

The application provides utilization projections and assumptions in Section III.1. While the rationale for the projected volume growth by service is provided in the application, many of the assumptions are unreasonable. Page 86 of the application projects utilization for CSC, based on the physician support letters. The physicians who will practice at CSC will all be performing cases at a facility in Caldwell, Burke or Catawba counties before CSC opens, from which they will shift cases to CSC. The following table shows the total cases projected for CSC from CMH physicians, who currently perform or will be performing these cases at CMH and Hancock prior to the opening of CSC.

Physician	*Current Facility*	*Total PY 1 Cases*
Bast	Caldwell Memorial	280
Jenkins	Caldwell Memorial	300
Keverline	Caldwell Memorial	250
Pezzi	Caldwell Memorial	240
Stanislaw	Caldwell Memorial	300
Purcell	Caldwell Memorial	200

Jaggers	Caldwell Memorial	50
Hershman	Caldwell Memorial	175
Pantiel	Caldwell Memorial	150
Young	Caldwell Memorial	50
Hannibal	Caldwell Memorial	70
Nenow	Caldwell Memorial	50
Total		**2,115**

Thus, CSC projects that 2,115 surgical cases will shift from CMH/Hancock to CSC in Project Year 1.

On page 97 of the application, CSC projects surgical utilization for CMH and Hancock, including after the opening of the ASC and the shift of cases to CSC. The middle column of the table shows the percentage and number of cases projected to shift, by specialty. Notwithstanding differences between the listed specialties and the surgeons' specialties (*i.e.* general surgeons performing GI cases), the sum of the total number of cases to shift is only 2,028, which is less than the shift projected above.

Moreover, it is apparent that there are inconsistencies between the projections in the physician letters and those in the table on page 97. For example, on page 97, the application projects 360 podiatry cases to shift; the sum of the projected shifts in Drs. Jenkins' and Pantiel's letters is 450 cases. Similar discrepancies exist for other specialties as well. As a result, if one believes the projections for CSC, then fewer cases will remain at CMH than are projected in the application. The application does state on page 96 that "the applicants confirmed that the volume estimates for CSC properly take into account continued surgical volume at CMH consistent with the projections as described in this application." However, that statement does not explain the differences in the projections. If the physician letters projected 2,115 cases to shift from CMH and Hancock, then at least that number should be projected to shift. The physician letters provide no support for the number of cases projected to remain at CMH, particularly when fewer cases are projected to shift than are referenced in the letters.

Further, the projected utilization at CMH after the shift of cases to CSC is based on unreasonable growth assumptions. The table on page 98 provides the rationale behind the assumptions. For general surgery and endoscopy, the application projects 5.0 percent growth for outpatient cases, based on "replacement surgeon recruited in 2015 with increases in productivity; additional surgeon and gastroenterologist to be recruited." However, this is a similar rationale provided on page 83 to support the growth from 2015 to 2017. If the replacement surgeon is already in place in 2015, even with a ramp-up in growth,

as projected for 2016 and 2017, since it is a replacement surgeon, there is no evidence that the utilization would continue to increase as projected, neither is any support provided for an increase in productivity at CMH. With regard to orthopedics, the application projects the increase to be based on recruitment in 2014, additional surgeons joining the medical staff, and increased productivity. Once again, the application provides no support for its ongoing increase in volume from a surgeon recruited five years earlier, nor does it provide any evidence that additional orthopedic surgeons from existing practices will join the medical staff (see discussion below). As with general surgery, no explanation is provided for the "increases in productivity." For the other specialties, the application makes similar assertions without providing support; of particular note is the expectation that utilization at CMH will increase in 2018 and 2019 for vascular and podiatry because of "increases in productivity at CSC." The application provides no evidence that such enhanced productivity at CSC would drive increases in utilization at the hospital; rather, the application refers to enhanced productivity at the ASC to drive utilization there.

CHSBR also points to the inherent inconsistency in CSC's assumptions. The application states repeatedly that the proposed project is needed to attract and retain physicians to Caldwell County; however, the application also states that CMH has successfully recruited physicians recently. The application also projects continued success recruiting surgeons during the interim project years—before the proposed project is approved or operational. Clearly, the application demonstrates that the hospital has been able to recruit physicians without a freestanding ASC and expects to continue doing so. In addition, the application does not demonstrate that the project will result in additional physicians practicing in Caldwell County. Rather, it projects that surgeons practicing in other counties will shift some of their cases—mostly those performed on non-Caldwell patients—to the proposed ASC.

As a result of these inconsistencies and substantial errors, the application fails to support its utilization projections at CMH with reasonable assumptions, and the application should be found non-conforming with Criterion 3.

Inconsistent Information Regarding the ASC's Lower Charges

The application presents the "need" for a freestanding ASC to provide surgical care in a lower cost setting. Information provided in the management agreement, however, indicates that patients may not benefit from the lower costs touted in the application. In Exhibit 5, Sections II.1.D and F of the management agreement provide the manager, CMH, the ability to "negotiate fee payment methods," and to determine and set "patient charges for services provided by the Center." This language would likely enable the hospital to use its market power

to negotiate more favorable (in this context, meaning higher) rates for the ASC than the ASC would be able to negotiate on its own. Further, this would appear to remove the financial and administrative separation between the hospital and the ASC, which is required by Medicare. Alternatively, if the ASC is financially and administratively separate from the hospital, then the activities of the manager might be prohibited by federal and state antitrust laws that would forbid price fixing or collaboration on price by entities without sufficient financial or clinical integration. Either way, the management relationship proposed for the ASC is problematic. As such, the projected costs and charges in the application are not based on reasonable assumptions, **and the application should be found non-conforming with Criterion 5**.

Issues with the Facility Design

The line drawings in Exhibit 22 show that the facility appears to be poorly designed and may not be able to be developed as proposed. Specifically, the layout of the ASC is not optimally designed for infection control purposes. The loading dock is adjacent to the Sterile Core, with a door that leads directly from Receiving into the Sterile Core. The Soiled Utility room also appears too small to effectively serve the entire facility. It is also unclear if one of the PACU rooms is intended to be used for isolation, given that none of them include an anteroom. CHSBR notes that the CON Section has in past reviews, including reviews of CHSBR applications, asked the Construction Section to review line drawings submitted in CON applications to determine whether they are reasonable or able to meet applicable codes. Given these issues, and to remain fair and consistent, CHSBR believes that the CON Section should ask the Construction Section to review the drawings in this application as well.

Based on the issues discussed above, CHSBR believes that the application should be found non-conforming with Criterion 12.

Unsupported and Unreasonable Payor Mix Assumptions

The application contains several support letters from physicians, many of which contain detailed information about the patients and cases the surgeons intend to perform. This information was used to determine support for many of the assumptions in the application, including the utilization projections and the patient origin. The changes in both of these items—utilization and patient origin—compared to the historical utilization and patient origin at CMH, demonstrate the impact that the physicians shifting cases would have on the project. The letters fail to contain ***any*** information about the payor mix for the physicians who would practice at the ASC and who propose to shift cases, for which the payor mix would most likely be similar to their historical payor mix, to

the ASC. Instead, the letters contain a scripted statement that the physicians support the projected payor mix at the ASC, which they contend would be the same as the hospital's outpatient surgery payor mix for procedures performed by a different group of physicians, including many who do not currently practice at the hospital. The language regarding this support is focused on the outreach to low income and medically underserved patients.

While CHSBR understands that CMH is a mission-driven not-for-profit hospital, even with an intensive marketing campaign and outreach to the medically underserved, it is simply not reasonable to project such a dramatic shift in the origin of patients, the types of specialties and cases being performed, without also projecting a change in payor mix. Although CSC contrasts its policies to those of Viewmont Surgery Center (on page 71 of the application) to attempt to demonstrate that CSC will be more open to the medically underserved than Viewmont, and therefore more likely to have a payor mix that matches that of the hospital, information in the application actually shows that the policies at CMH and Viewmont are similar. On page 71 of the application, CSC states that Viewmont requires payment of co-pays and deductibles on the day of surgery, and that all payment is required in advance for those without insurance. It is likely that most if not all of the surgical cases performed at Viewmont are elective, not emergent; the requirement of payment in advance in cases of elective cases is not unusual. The policy presented on pages 329 and 330 of the application shows that CMH actually has similar policies—for its emergency patients—including payments of at least $100 from commercial and uninsured patients. Please note that CHSBR is not criticizing CMH's financial policies, but rather explaining why it is not reasonable to assume that patients will come to the proposed ASC because of any significant differences in policies with other facilities. Moreover, in an elective setting such as an ASC, patients must first be treated by a surgeon who determines that they need surgery. Thus, it is usually the policy of the surgeon, not the ASC, that determines the payor mix, particularly the amount of underserved. This is different from a hospital, that must take all patients presenting in the Emergency Department without regard to their ability to pay—including providing surgical care if that is needed. Thus, it is not reasonable to assume that the payor mix of the ASC will mirror that of CMH.

In addition, the projected patient origin for CSC is different from CMH and pulls more patients from other counties, particularly Burke and Catawba. The populations of the counties being served by CSC and CMH are quite different, which will impact the payor mix of the facility. As shown below, the population of Catawba County, in particular, is significantly different from that of Caldwell County.

Factor	*Caldwell*	*Catawba*
Percent of Population 65+	18.0%	16.5%
Median Age	42.9	40.8
Average Income	$41,708	$60,215
Median Income	$31,310	$44,164

Source: Nielsen/Claritas demographic reports for 2015

As shown, the population of Catawba County, the source of the greatest projected shift of patients to the ASC, has a smaller percentage of the county residents aged 65 or older, and is a younger and more affluent population. Similar to the analysis conducted in the Agency Findings for the first application to develop CSC, an analysis of the population this application projects to serve demonstrates that it would relocate the existing operating rooms to a location where it would serve a much higher percentage of patients from Catawba County, which has a lower percentage of patients in medically underserved categories.

In addition, the application projects to serve a different mix of specialties and different types of cases at CSC than are currently performed at CMH. The physician letters even point to this fact by providing the limited types of cases that they intend to perform at the ASC, stating that some are not appropriate for care in an ASC. CSC has offered no explanation why the payor mix as CSC would mirror that at CMH when the case mix is different.

Given the significant differences in the population to be served and the types of cases to be performed, the projected payor mix for CSC is not based on reasonable assumptions. **Given these factors, CSC should be found non-conforming with Criteria 5 and 13(c).**

Failure to Demonstrate that the Surgeons Will Seek Privileges at Caldwell Memorial Hospital

The service area for the project, as defined in the special rules, is Caldwell County, and the only acute care hospital in Caldwell County is CMH. Therefore, according to the language in the rules, the application must document that the physicians who will practice at the ASC will be privileged at CMH, not any other hospital.

In addition, the issue of privileging is important for several reasons. First, for continuity of care, it is important that physicians who practice at the ASC be able to admit and follow patients at the hospital in the same county. Second, it is a requirement of the criteria and standards for operating rooms in CON

applications. Third, hospital privileges are usually accompanied by some responsibility for the privileged physician to take call or unassigned patients that present at the hospital. This ensures patients in need of specialty care can get that care, even without an ability to pay for the care. Finally, this issue addresses a problem faced by many hospitals—having a sufficient number of physicians in a specialty to provide coverage for inpatient care.

In multiple locations, the application states that the physicians who supported the proposed project "are committed to obtain active medical staff privileges at Caldwell Memorial Hospital." The application references Exhibits 8 and 10 for support of this statement. Exhibit 8 includes a letter from Ms. Easton, President and CEO of CMH, with a table listing the supporting physicians and their intent to obtain privileges. Since many of the physicians who wrote letters of support for the project do not currently practice in Caldwell County or at CMH, obtaining privileges at CMH requires action by those physicians to become admitted to the medical staff at CMH.

Notwithstanding the language in the application and Ms. Easton's letter to the contrary, **the letters from the physicians do not contain any commitment to obtaining privileges at Caldwell Memorial Hospital**. In fact, the letters focus solely on the cases to be performed at the ASC, without any mention of CMH. Moreover, **the letters imply that the physicians will not be privileged at CMH**. The letters from these physicians indicate that they are unwilling to use the existing Hancock Surgery Center because of its location in Lenoir. Thus, if these surgeons believe that the "'problem' with Hancock is its location," then it is unreasonable to assume that these surgeons, who do not perform cases at Hancock or CMH because of their locations in Lenoir, would become active members of the medical staff at CMH nor that they will perform cases there in the future.

The application also refers to Exhibits 18 and 19, the medical staff by-laws and privileging criteria to support the assertion that the physicians will all have to be privileged at CMH. These documents, however, show that the physicians will not have to be privileged at CMH. In particular, Article 4.1.A.(ii) of the medical staff by-laws (page 262) state that physicians practicing at the ASC must only hold admitting (not active) privileges at a hospital within 15 miles of the ASC. Given the ASC's location, that would include hospitals other than CMH, notably Frye Regional Medical Center (5.1 miles) and Catawba Valley Medical Center (12.3 miles), where some of the supporting physicians already have privileges. Given surgeons' busy schedules, which include clinic time, surgery time and time for rounds/follow up in the hospital, and given the requirements for being privileged discussed above, it is unlikely that surgeons will seek privileges at CMH, and the application fails to provide any evidence that they will do so. In

particular, one of the supporting physicians, Dr. Zook, currently has privileges and practices only at Carolinas HealthCare System - Blue Ridge Morganton, which is not within 15 miles of the proposed location for CSC. Thus, under the terms of the medical staff by-laws included in the application, he would be required to seek privileges at another hospital, yet the application provides no evidence of his intention to do so.

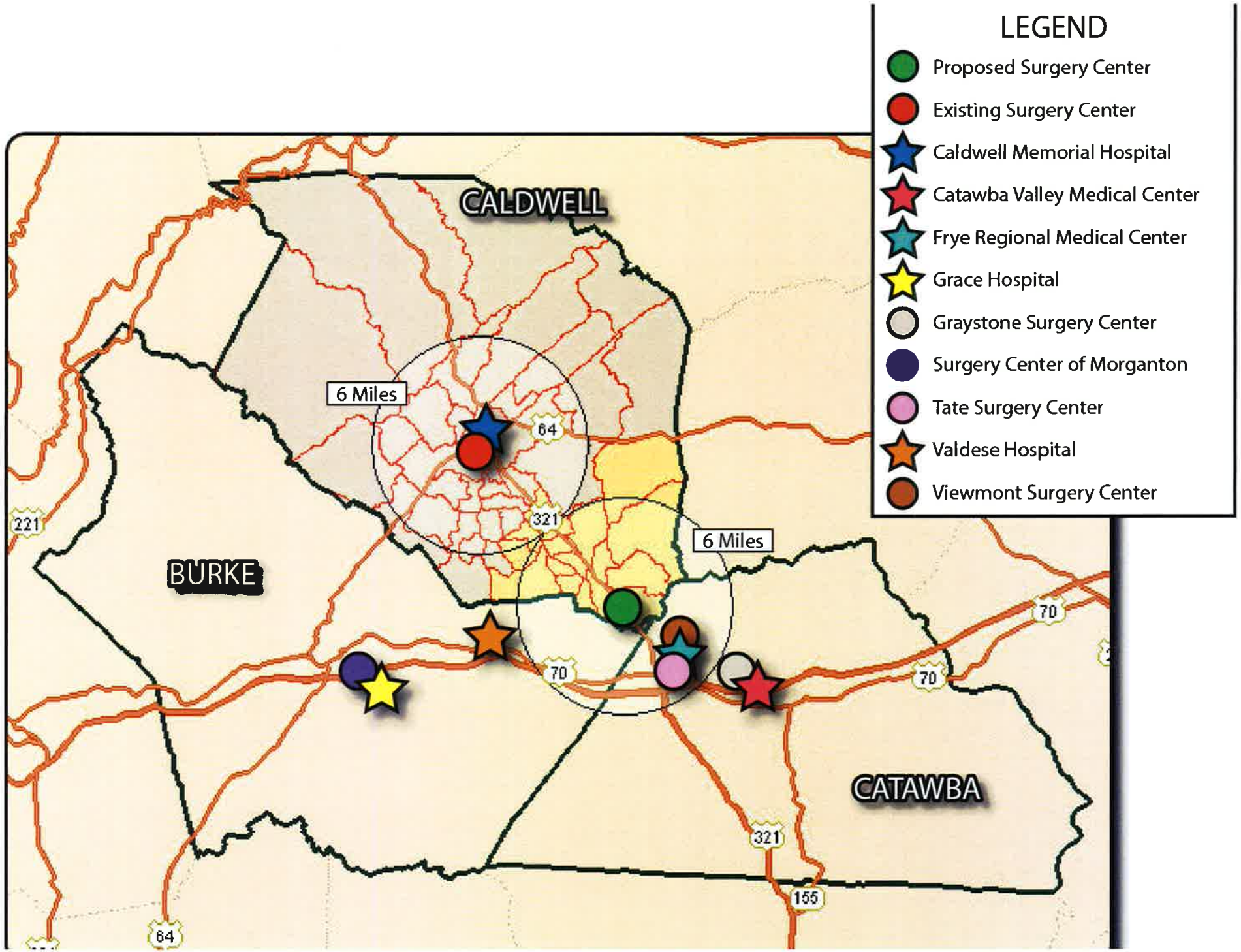
With regard to Dr. Zook in particular, CHSBR believes it would be unreasonable to approve the proposed project, which the application states is to positively impact access for Caldwell County patients, but projects patients from Burke County to leave their home county for care in Caldwell County. This is especially true when the Burke County patients served by Dr. Zook have benefitted from a substantial financial investment from CHSBR that enabled Dr. Zook to locate his practice in Burke County. As a not-for-profit hospital, CHSBR does not operate under a normal competitive environment when recruiting physicians to serve its patients. Rather, Stark laws require, among other things, that not-for-profit hospitals demonstrate the existence of a need in their community (as defined and clarified by Stark II, Phase III) for the physician being recruited, when the hospital uses tax-exempt funds to incentivize the physician. As part of its mission, CHSBR used excess funds to invest in improving the health of its community through the recruitment of Dr. Zook to Burke County. With the proposed project, CSC would profit financially from patients leaving Burke County, served by a physician that was recruited and incentivized to come to Burke County under strict Stark laws. Clearly this is an uneven playing field and not a typical competitive situation. In terms of the CON review criteria, it also represents unnecessarily duplication, given the availability of operating rooms in Burke County to serve those patients.

For these reasons, CSC should be found non-conforming with Criteria 6 and 8 and 10A NCAC 14C .2105(c).

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.

Attachment 1


LEGEND
Proposed Surgery Center
Existing Surgery Center
Caldwell Memorial Hospital
Catawba Valley Medical Center
Frye Regional Medical Center
Grace Hospital
Graystone Surgery Center
Surgery Center of Morganton
Tate Surgery Center
Valdese Hospital
Viewmont Surgery Center
CALDWELL
BURKE
CATAWBA
6 Miles
6 Miles
64
321
70
70
70
221
321
155
64

Attachment 2

Caldwell County Population Stats by Block Group
Population Data Estimates for 2014 from Claritas

2014 Data	Population in Block Groups Closer to Caldwell Surgery Center	Population in Block Groups Closer to Hancock Surgery Center		Caldwell County Total
Total Population	27,835	54,348		82,183
% of Caldwell County	33.9%	66.1%		100.0%
65+ Pop.	4,337	9,891		14,228
% 65+	15.6%	18.2%		17.3%
Median Age	41.6	43.0		42.5
White	25,693	46,026		71,719
African-American	324	4,118		4,442
Hispanic/Latino	1,262	2,904		4,166
Other	556	1,300		1,856
% White	92%	85%		87%
% African-American	1%	8%		5%
% Hispanic/Latino	5%	5%		5%
% Other	2%	2%		2%
Median Household Income	$34,814	$29,282		$30,927
Average Household Income	$48,459	$40,053		$42,827
Total Households	10,928	22,183		33,111
Households with Income Less than $35,000	5,491	13,050		18,541
% of Total Households	50%	59%		56%