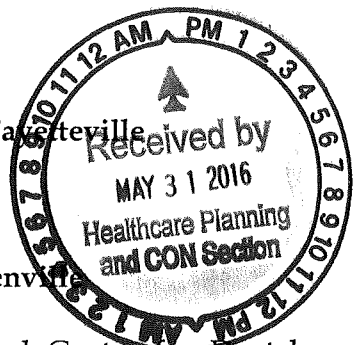

Comments on Valleygate Dental Surgery Center of Fayetteville

submitted by

Surgical Center for Dental Professionals of Greenville

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Surgical Center for Dental Professionals of Greenville (SCDP of Greenville) submits the following comments related to Valleygate Dental Surgery Center of Fayetteville's (VDSCF) application to develop a new dental surgery center. SCDP of Greenville'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, SCDP of Greenville 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 VDSCF, Project ID # J-11176-16.

GENERAL COMMENTS

While the comments below will discuss the multiple specific deficiencies in the VDSCF application that necessitate its denial, SCDP of Greenville believes that an overall comparison of the applications demonstrates the clear superiority of its proposed project over that of VDSCF. The VDSCF application has attempted to define need for the project in a way that best meets the needs of a small number of dentists associated with Knowles, Smith & Associates (KSA) who predominately serve pediatric patients.

There are numerous examples of VDSCF's focus on pediatric patients to the exclusion of adult patients throughout its application including:

- *"The proposed project's primary focus will be patients of pediatric dentists"* (page 30)
- *"Valleygate Dental Surgery Center of Fayetteville's primary focus will be pediatric dental surgery performed by pediatric dentists"* (page 31)

In its application, VDSCF ignores the need by adult patients to access licensed surgical facilities and limits their proposed service to mostly pediatric patients. In contrast, SCDP of Greenville proposes to serve both pediatric and adult dental patients who lack access to licensed surgical facilities. This difference is not merely one of opinion of one applicant versus the other; rather, it is clear from multiple independent parties that the need extends beyond the pediatric population:

- Dr. Mark Casey, Dental Director of the NC Division of Medical Assistance, who requested the availability of the facility to patients of all ages, as noted in the petition to the State Health Coordinating Council (SHCC) from KSA[1];
- Piedmont Health, which serves thousands of adults in need of access to licensed surgical facilities for dental cases requiring sedation;
- Advance Community Health, which serves patients of all ages in need of access to licensed surgical facilities for dental cases requiring sedation;
- The scores of dentists supporting SCDP of Greenville's application who plan to perform hundreds of adult cases per year;
- The North Carolina Board of Dental Examiners, which recently proposed new stricter rules for dentists using general anesthesia and sedation, which will effectively lower the number of general dentists who are allowed to perform sedation cases in their offices;
- VDSCF's consultant, who authored language in the petition to the SHCC which stated, "Children are only part of the need...Data on the percent of adults who need oral surgery are not easily found[2];"

Most importantly, the SHCC itself, rejected the concept proposed by KSA, which sought to limit the facilities to pediatric patients, but instead approved the need for facilities to serve both adults and pediatric patients. As stated in the *2016 State Medical Facilities Plan (2016 SMFP)*, the applicants *"shall provide the projected number of patients ... broken down by age (under 21, 21 and older)"* with the stated rationale of *"Access: Requiring service to a wide range of patients promotes equitable access to the services provided by the demonstration project facilities"* (emphasis added, Table 6D).

In fact, VDSCF argues in its application that the dental surgery center projects should, in fact, not be provided to a wide range of patients as required by the *2016 SMFP*, stating, "[i]*n summary, the pediatric population overwhelmingly dominates the group in need of licensed surgical operating room care. Only a small fraction of adults truly require care in an* [sic] *licensed operating room setting, and this need, has been, and is currently being met to satisfaction, by existing Hospitals and Ambulatory Surgery Centers nationwide"* (page 51). This is a clear disagreement with the requirement for a wide range of access by the dental ambulatory surgery center demonstration projects. SCDP of Greenville believes the opposite is true: pediatric dentists have access to existing licensed facilities, while the need for dental surgery for adults is not met by hospitals and ambulatory surgery centers. As noted in SCDP of Greenville's application, *"unlike a large majority of general dentists or other dental subspecialties, pediatric dentists must complete a required two to three year residency for training specific to providing care to patients in an operating room setting with the aid of an anesthesiologist. As a practical matter due to this distinction in training, while some hospitals do extend privileges to general dentists who have general practice residency*

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1 https://www2.ncdhhs.gov/dhsr/mfp/pets/2015/acs/0803_cumberland_dor_petition.pdf at page 3.

2 https://www2.ncdhhs.gov/dhsr/mfp/pets/2015/acs/0803_wake_dor_petition.pdf at page 8.

training, hospital bylaws generally include provisions to permit the privileging of pediatric dentists, but exclude general dentists and other dental subspecialties. (page 19). As such, pediatric dentists are able to attain privileges for surgery in licensed settings while a large majority of general dentists and other dental professionals do not currently have such access which precludes the ability to care for their adult patients in those settings.

Notably, Cape Fear Valley Health System (CFVHS), located in Cumberland, Hoke, Bladen and Harnett counties has repeatedly offered additional surgical time to KSA dentists, both in writing and verbally. In fact, KSA dentists are utilizing CFV Hoke Hospital operating rooms which was not disclosed in the VDSCF application. Additional access to time and space at CFV Hoke Hospital and other CFVHS operating rooms has not been pursued by KSA. The letters in Attachment 1, submitted in response to the KSA Petitions in March and July 2015 indicate that CFVHS has available surgical space at multiple surgical sites. In addition, at the June 2015 Dental Stakeholders Meeting held by the SHCC, CFVHS again verbally offered available surgical space to KSA dentists. KSA has not pursued these options. In contradiction, VDSCF stated in its application that "[h]*ospitals in Cumberland and Robeson counties have limited or refused block time to general and pediatric dentists. Highsmith Rainey provides an average of 4.8 blocks per week. Cape Fear Memorial and Southeast Regional offer no blocks. Travel distance from the dental office becomes a balancing issue, especially when cases are few. The new First Health Hoke hospital has made overtures for future availability*" (pages 80-81). KSA's experience is evidence of the ability of pediatric dentists to attain privileges in licensed settings in contrast to the large majority of general dentists and other dental professionals.

Moreover, VDSCF's assertion that only a small fraction of adults require care in a licensed facility is not supported. First, Valleygate Dental Surgery Center of Raleigh's (VDSCR) certificate of need application for a dental single specialty ambulatory surgical facility demonstration project in Region 1 assumes that its largest referral source will be WakeMed, which provides 22 percent of its dental surgery cases to adults (please see Surgical Center for Dental Professionals of Raleigh's comments on VDSCR). Thus, KSA is or should be aware that current providers serve a substantial number of adult patients. Similarly, the organizations in the bulleted list above recognize the need for adult and pediatric patients. Finally, the North Carolina Board of Dental Examiners focus on changing the rules for sedation is driven by a concern with safety in office settings for adults and children. Thus, VDSCF's assertion that the vast majority of adults do not require access to the proposed dental surgery center is contrary to the Board's actions of addressing office-safety concerns as a reaction to two recent adult fatalities in North Carolina dental offices.

VDSCF further limits access to its facility by requiring all practitioners using the facility to be licensed for sedation: "[g]*eneral dentists without specific certification for sedation will not be permitted to perform dental surgery at Valleygate Dental Surgery Center of Fayetteville*" (page 30).

While this requirement may be clinically necessary since VDSCF does not require anesthesiologist coverage for all its cases, as SCDP of Greenville does, it limits access to the facility to only those dental professionals with such licensure, which is approximately 500 of the 5,000 dentists statewide, or only 10 percent. General dentists who lack this certification are able to expertly perform these cases and would be eligible to be credentialed at SCDP of Greenville based on their expertise and not based on sedation certification. SCDP of Greenville will provide the anesthesiologist coverage so that general dentists can bring their patients to the surgery center and perform the case, ensuring continuity of care. Under VDSCF's model, any dental professional without the certification would be required to refer the case to another dental professional with access to the surgery center.

Again, VDSCF's project is contrary to requirements for the demonstration project as outlined in the *2016* SMFP which states that "[t]*he proposed facility shall provide open access to non-owner and non-employee oral surgeons and dentists*" with the stated rationale of "*Access: Services will be accessible to a greater number of surgical patients if the facility has an open access policy for dentists and oral surgeons*" (Table 6D). SCDP of Greenville does not believe that a facility which limits access to only 10 percent of the dental providers in the state is an effective option for this demonstration project.

Further, VDSCF's focus on pediatric patients served by pediatric dentists limits the project to dental professionals who already have access to licensed ambulatory surgery center settings today, as noted above. VDSCF's project will not provide access to general dentists and other dental professionals who cannot attain privileges due to hospital by-laws.

Based on these issues, VDSCF's application does not meet the requirements of the demonstration and should be found non-conforming with Criterion 1. As such, VDSCF should be denied.

APPLICATION-SPECIFIC COMMENTS

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

(1) Failure to document access to funds;
(2) Unsupported methodology and assumptions for utilization;
(3) Unsupported methodology and assumptions for age and payor mix; and,
(4) Unreasonable financial projections.

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

FAILURE TO DOCUMENT ACCESS TO FUNDS

The VDSCF application does not demonstrate that the applicants have access to the capital and operating funds necessary to develop the project.

The named applicants in this review are VFD Real Estate Partners, LLC (VFD) and Valleygate Dental Surgery Center of Fayetteville, LLC (VDSCF). Sections I and XI of the application propose that VFD will own the real estate and construct the facility, and VDSCF will lease and operate the facility.

According to Section VIII, VFD is responsible for $3,873,554 of the capital cost of the project, and VDSCF is responsible for $967,642 of the capital cost for consultant fees and to purchase necessary furniture and equipment. In addition, according to Section IX, VDSCF is responsible for the total working capital of $788,336. Therefore, VFD must demonstrate the availability of $3,873,554 for capital needs, and VDSCF must demonstrate the availability of $1,775,978 for capital and operating needs, in order for the application to be conforming with Criterion 5.

The VDSCF application proposes to finance both capital and operating needs through loans from First Citizens Bank. In this regard, the applicants state on page 201 that Exhibit 42 contains two letters from First Citizens: (1) one showing the bank's willingness to loan VFD the necessary capital to fund the development of the building; and (2) one showing the bank's willingness to loan VDSCF the necessary capital to fund the equipment purchase and working capital.

However, Exhibit 42 contains just one letter from First Citizens, expressing interest *only* in loaning funds to VFD to construct the building, which First Citizens understands would be approximately $4,000,000. There is nothing in that letter which suggests a willingness by First Citizens to loan *more than* $4,000,000 to VFD for the construction cost of the building, or to loan *any* funds to VDSCF for any purpose.

The VDSCF application contains no alternative source of funding for VDSCF's capital and operating needs. Neither the pro forma projections nor the exhibits to the application contain any information regarding current assets or other funds which could be used for the project.

In *Retirement Villages, Inc. v. NC DHHS*, 124 N.C.App. 495, 477 S.E.2d 697 (1996), the North Carolina Court of Appeals held that the applicants which had been initially approved by the CON Section should have been found non-conforming with Criterion

5, because there was no information in the application showing that the applicants had access to funds for the project. Specifically, the Court found:

> that in cases where the project is to be funded other than by the applicants, the application must contain evidence of a commitment to provide the funds by the funding entity. We hold that without such a commitment, an applicant cannot adequately demonstrate availability of funds or the requisite financial feasibility.

Retirement Villages, 124 N.C.App. at 499, 477 S.E.2d at 699 (emphasis added).

Similarly, because there is nothing in the VDSCF application from First Citizens indicating its willingness to loan over $1.77 million to VDSCF, the applicants have not and cannot demonstrate availability of funds for VDSCF's capital and operating needs, and are non-conforming.

This is not an error that VDSCF can fix. Agency rule 10A N.C.A.C. 14C.0204 prohibits VDSCF from amending its application to correct this deficiency. As this is a competitive review, requiring a public hearing, there will be no expedited review, and there is no statutory basis for the Agency to request additional information from VDSCF during the review. G.S. 131E-185(a2).

Since the *Retirement Villages* decision, the Agency has consistently found in subsequent decisions that where there is insufficient information in the application to demonstrate the availability of funds for capital and operating needs, the application must be disapproved. *See* Required State Agency Findings, Duke University Project I.D. No. J-5938-98, pp. 21-22; Required State Agency Findings, KND Development 50, L.L.C. d/b/a Kindred Hospital Charlotte, Project I.D. No. F-7993-07, pp. 11-12; Required State Agency Findings, Onslow MRI, LLC, Project I.D. No. P-8332-09, pp. 56-59 (Copies of pertinent portions of these Findings are included in Attachment 2). There is no reason to diverge from these past decisions.

For all of these reasons, the VDSCF application must be found non-conforming with Criteria 4, 5, and 12, and disapproved.

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR UTILIZATION

On pages 133-137 of its application under the heading "Part 1: Utilization Projections for Entire Facility", VDSCF provides contradictory and unsupported statements which indicate that its utilization methodology is unreasonable.

On page 134 of its application, VDSCF states "[p]*articipating members or dentists interested in referring to VDSCF at the time of this application performed approximately 2,282 dental surgical procedures under general anesthesia in 2014. This represented approximately 27.9 percent of the need estimated in Section III.1.(b), Table III.16 (2,282 / 7,946 = 27.9%).*" This estimate of 2,282 procedures is inconsistent with table provided on the same page which shows total estimated historical OR volumes from VDSCF referral sources of 3,230 cases. The excerpt below demonstrates these two inconsistent statements from page 134 of the VDSCF application:

> Participating members or dentists interested in referring to VDSCF at the time of this application performed approximately 2,282 dental surgical procedures under general anesthesia in 2014. This represented approximately 27.9 percent of the need estimated in Section III.1 (B), Table III.16 (2,282 / 7,946 = 27.9%). The DMA data analysis for 2015, which is contained in Exhibit 47, showed 2,011 Medicaid general anesthesia cases for the same area, confirming the reasonableness of the dentists' estimates. The applicant found the DMA data did not capture all of the cases in its member records.

Table IV. 2 – Estimated Historical OR Volumes from VDSCF Referral Sources

Source	Cases
KSA	1,418
Dr. Collins	144
Dr. Stokes and Dr. Bridgers	360
Dr. Vissicelli	120
Dr. Dunston	240
CommWell	408
Goshen	540
Total	***3,230***

Source: Actual KSA practice records and estimates

Based on this inconsistency, it is not possible to determine the historical case volumes for VDSCF's referral sources. The ~900 case difference between the two statements is material. In the third project year, VDSCF projects to perform 4,156 cases of which 900 cases constitutes more than 20 percent. If its volume were 900 cases fewer, VDSCF would require less surgical room capacity and generate less revenue. Thus, its demonstration of need and financial feasibility is unsupported. Further, VDSCF's

projections for the number of children and adults treated and the amount of Medicaid and charity care patients served would also be lower.

There are further inconsistencies regarding utilization in its application. VDSCF provides three different estimates of KSA's expected referral volume – it is impossible to determine whether any are accurate. As shown in the table above, VDSCF states that KSA will be the source for 1,418 cases. However, support letters included in the application in Exhibit 26 from KSA dentists include specific supports letters totaling 110 cases monthly or only 1,320 cases annually. Please see the excerpt below from the summary table in Exhibit 26 which includes four Village Family Dental/KSA pediatric dentists (Ravel, Olsen, Burke, and Dodds) with a total of 110 monthly referrals. Of note, Dr. Faith McGibbon is listed in the table with 130 to 220 cases monthly which refers to KSA in total, per the support letter. Thus, Dr. McGibbon's letter states the total KSA volume will be 1,560 to 2,640 cases annually.

Pediatric Dentist: Support and Referrals to Valleygate Dental Surgery Center of Fayetteville

Name	Specialty	Organization	Location	Referrals / Mo LOW	Referrals / Mo HIGH
Yvetter McAlister Stokes, DDS	Pediatric Dentist	Highland Pediatric Dental	Fayetteville		30
Carey M. Collins, DDS, MS	Pediatric Dentist	Lumberton Pediatric Dentistry	Lumberton	12	16
Bryan Dunston	Pediatric Dentist	Sandhills Pediatric & Family Dentist	Sanford		20
Daniel Ravel, DDS	Pediatric Dentist	Village Family Dental	Fayetteville		30
Jordan Olsen, DDS, MS	Pediatric Dentist	Village Family Dental	Raeford		30
Richard M. Burke, Jr, DMD	Pediatric Dentist	Village Family Dental	Fayetteville		30
Anne P. Dodds, DDS, PhD, BSD, MPH	Pediatric Dentist	Village Family Dental	Fayetteville		20
Vincent Vissichelli, DMD	Pediatric Dentist	Firehouse Kid's Dentistry	Spring Lake		10
Jose Cangas, DDS	Pediatric Dentist	Dental Derby	Southern Pines		20
Faith McGibbon, DDS	Pediatric Dentist	Village Family Dental	Fayetteville	130	220

So VDSCF provides three different estimates of KSA volumes as follows:

- 1,418 cases annually per page 134 of the application
- 1,320 cases annually per specific support letters from Ravel, Olsen, Burke, and Dodd included in Exhibit 26
- 1,560 to 2,640 cases annually per Dr. McGibbon letter included in Exhibit 26 referring to KSA in total

These referral estimates are the central driving assumption for its projected utilization. VDSCR's projected market share and its projected volumes are driven entirely by these referral estimates. As shown in the discussion above, these referral estimates are unsupported and unreasonable.

VDSCF has not demonstrated the need for the proposed project and its application should be found non-conforming with Criteria 3, 4, 5, and 12. As such, VDSCF should be denied.

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR AGE AND PAYOR MIX

VDSCF's projections for the percent of patients by age group and by payor class are unsupported and unreasonable. As VDSCF states on page 176 of its application, it determined the number of children and adult cases in year two by multiplying its "*total projected cases served in year two from Table IV.5 by the estimated percent of persons over 21 (adults) in year two from Table IV.6 (8.82 percent).*" As shown in Table IV.7 on page 137, the 8.82 percent figure is the percentage of total Medicaid statewide dental anesthesia cases in hospitals and ASCs that were over 21 years of age. VDSCF assumes that the age mix of its patients, which are derived from specific referral sources as identified in the preceding section, will be identical to the age mix of Medicaid patients statewide. This is unreasonable. First, VDSCF provides no information to indicate that its age mix will be identical to that of the Medicaid population statewide. Second, VDSCF provides no information to indicate that the age mix of patients in the Cumberland County area are identical to the Medicaid population statewide. Finally, VDSCF makes no attempt to account for the age mix for its specific referral sources which include KSA, two community organizations, and several other dental professionals. VDSCF did not adjust its projected age mix to account for the age mix of its referrals sources and thus its assumptions are unreasonable. Similarly, VDSCF's projections for payor mix by age group are based on the historical payor mix for KSA and makes no attempt to adjust for its non-KSA referral sources' payor mix. This is also unreasonable.

Additionally, VDSCF does not provide estimated payor mix for charity care and self-pay patients separately as required by Criterion 10-Demonstration Project. This is important, not only because it is required by the Demonstration Project criterion, but also because the difference between charity care and self-pay patients in dental practices is important. Dental insurance is not as commonly held by patients as healthcare insurance, for example. Therefore, a significant number of patients are truly "self-pay;" that is, they have the financial means to pay for dental care and choose to do so out-of-pocket. These patients are not charity care patients who do not have the financial means to pay the full cost of care out-of-pocket. By combining charity care and self-pay patients and presenting them as charity care, VDSCF has overstated its charity care contribution.

As the projected age and payor mix is unreasonable, VDSCF's financial projections are also unreasonable.

VDSCF has not demonstrated that its age mix, payor mix, or financial assumptions are supported and its application should be found non-conforming with Criterion 5 or 13(c) nor can they be used to show comparative superiority or conformity with the dental single specialty ambulatory surgical facility demonstration project. As such, VDSCF should be denied.

UNREASONABLE FINANCIAL PROJECTIONS

VDSCF proposes to provide ancillary services to the dental surgery cases, including crowns, X-rays, and panorex images. VDSCF states on page 33 that it will perform dental crowns and pages 34 and 38 discuss dental X-ray and panoramic X-ray. The equipment list in Section VIII, page 195 of the application includes X-ray equipment. However, the VDSCF's pro forma financial statements contain no revenue or expenses associated with these services. VDSCF includes an assumption for average charge on page 241 and an assumption other revenue (anesthesia) assumption on page 242 with no discussion of crowns, X-rays, or panorex images. As discussed in the assumptions within SCDP of Greenville's pro forma financial statements, crowns (based on reimbursement for the supplies used by dental professionals), X-rays, and panorex images are included as other revenue and are billed separately from the bundled charge. SCDP of Greenville's dental supplies expenses includes all supplies associated with its cases. Therefore, VDSCF fails to demonstrate that the financial projections are based on reasonable assumptions and it should be found non-conforming with Criterion 5. Moreover, given the differences in the range of ancillary services provided by the two applicants, as well as the lack of information in the VDSCF application regarding the revenue and expenses for the crowns and images it proposes to provide, the applications cannot be appropriately compared with regard to revenue and expenses.

VDSCF has not demonstrated that its financial projections are reasonable and its application should be found non-conforming with Criterion 5 nor can they be used to show comparative superiority. As such, VDSCF should be denied.

GENERAL COMPARATIVE COMMENTS

The VDSCF and SCDP of Greenville applications each propose to develop a dental single specialty ambulatory surgical facility demonstration project in Region 3 in response to the *2016 SMFP* need determination. SCDP of Greenville acknowledges that each review is different and therefore, that the comparative review factors employed by the Project Analyst in any given review may be different depending upon the relevant factors at issue. Given the nature of the review, the Analyst must decide which comparative factors are most appropriate in assessing the applications.

In order to determine the most effective alternative to meet the identified need determination, SCDP of Greenville reviewed and compared the following factors in each application:

- Conformity with the Need Determination
- Documentation of Dental Professional Support
- Geographic Access
- Quality of Care
- Access for Health Professional Training Programs
- Access by Underserved Groups
- Revenue
- Operating Expenses

SCDP of Greenville believes that the factors presented above and discussed in turn below should be considered by the Analyst in reviewing the competing applications.

Conformity with the Need Determination

The application submitted by VDSCF is non-conforming to the need determination in the *2016 SMFP* for a dental single specialty ambulatory surgical facility demonstration project in Region 3. In contrast, the application submitted by SDCP of Greenville is conforming to the need determination.

The need determination identifies 11 criteria. Of note, VDSCF is non-conforming with at least four of those criteria as discussed below.

#	*Criterion*	*VDSCF*	*SCDP of Greenville*
2	**The proposed facility shall provide open access to non-owner and non-employee oral surgeons and dentists**	Non-conforming	Conforming

As discussed above, VDSCF will not provide open access to non-owner and non-employee oral surgeons and dentists. By its own statements in the application, VDSCF's *"primary focus will be pediatric dental surgery performed by pediatric dentists"* (page 30). This primary focus means that other oral surgeons and dentists will have less access. There can be no other interpretation.

Further, VDSCF's focus on pediatric patients served by pediatric dentists limits the project to dental professionals who already have access to licensed ambulatory surgery center settings today. As noted in SCDP of Greenville's application, *"unlike a large majority of general dentists or other dental subspecialties, pediatric dentists must complete a*

required two to three year residency for training specific to providing care to patients in an operating room setting with the aid of an anesthesiologist. As a practical matter due to this distinction in training, while some hospitals do extend privileges to general dentists who have general practice residency training, hospital bylaws generally include provisions to permit the privileging of pediatric dentists, but exclude general dentists and other dental subspecialties. (page 19). As such, a large majority of general dentists and other dental professionals do not currently have access to hospital-based operating rooms. VDSCF's project will not provide access to these dentists.

VDSCF further limits access to its facility by requiring all practitioners using the facility to be licensed for sedation: "[g]*eneral dentists without specific certification for sedation will not be permitted to perform dental surgery at Valleygate Dental Surgery Center of Fayetteville*" (page 30)

While this requirement may be clinically necessary since VDSCF does not require anesthesiologist coverage for all its cases, as SCDP of Greenville does, it limits access to the facility to only those dental professionals with such licensure, which is approximately 500 of the 5,000 dentists statewide, or only 10 percent. General dentists who lack this certification are able to expertly perform these cases and would be eligible to be credentialed at SCDP of Greenville based on their expertise and not based on sedation certification. SCDP of Greenville will provide the anesthesiologist coverage so that general dentists can bring their patients to the center and perform the case, ensuring continuity of care. Under VDSCF's model, any dental professional without the certification would be required to refer the case to another dental professional with access to the center.

VDSCF's application does not meet the requirements of Criterion 2-Demonstration Project. As such, VDSCF is comparatively inferior to SCDP of Greenville.

#	*Criterion*	*VDSCF*	*SCDP of Greenville*
6	**The proposed facility shall provide care to underserved dental patients, including provision of services to charity care patients and Medicaid recipients equal to at least three percent and 30 percent, respectively, of its total patients each year**	Non-conforming; 5.3% Charity Care and 88.5% Medicaid projected (page 180)	Conforming; 4.2% Charity Care and 63.9% Medicaid projected (page 167)

Based on the data presented in the applications, VDSCF projects a higher percentage of total Medicaid patients and a higher percentage of total charity care patients.

As discussed above, VDSCF's proposed payor mix is based on unsupported assumptions. VDSCF's projections for payor mix are based on the historical payor mix for KSA and make no attempt to adjust for the payor mix of its other referral sources.

As noted above, VDSCF's projections for patients by age group are unsupported, therefore, their Medicaid payor mix projections are unsupported. Finally, VDSCF does not provide estimated payor mix for charity care and self-pay patients separately, as shown in the excerpt below, as required by Criterion 10-Demonstration Project.

Table VI. 9 – Estimated Payer Mix: VDSCF Year Two

Payer	Cases Under 21	Cases 21 and Over	Total	Percent
Notes	*a*	*b*	*c*	*d*
Self Pay/ Indigent/ Charity	69	131	201	5.3%
Medicare / Medicare Managed Care	0	0	0	0.0%
Medicaid	3,303	67	3,371	88.5%
Commercial Insurance	71	133	205	5.4%
Managed Care	0	0	0	0.0%
Military	29	3	32	0.9%
Total	*3,473*	*336*	*3,809*	*100.0%*

See page 180 of VDSCF application.

This is important, not only because it is required by the Demonstration Project criterion, but also because the difference between charity care and self-pay patients in dental practices is important. Dental insurance is not as commonly held by patients as healthcare insurance, for example. Therefore, a significant number of patients are truly "self-pay;" that is, they have the financial means to pay for dental care and choose to do so out-of-pocket. These patients are not charity care patients who do not have the financial means to pay the full cost of care out-of-pocket. By combining charity care and self-pay patients and presenting them as charity care, VDSCF has overstated its charity care contribution.

Even if VDSCF's unsupported payor mix was accepted, the differences in patient population between the two facilities makes a comparison unreasonable, particularly, for Medicaid. As noted throughout these comments, VDSCF's primary focus is pediatric dental surgery on pediatric patients. VDSCF projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Greenville projects 34.5 percent. This difference in patient population results in differences in payor mix, and, as will be discussed later, revenues and expenses. As such, a reasonable comparison cannot be made.

VDSCF's application does not meet the requirements of Criterion 6-Demonstration Project. As such, VDSCF is comparatively inferior to SCDP of Greenville.

#	*Criterion*	*VDSCF*	*SCDP of Greenville*
10	For each of the first three full federal fiscal years of operation, the applicant(s) shall provide the projected number of patients for the following payor types, broken down by age (under 21 or 21 and older): charity care, Medicaid, TRICARE, private insurance, self-pay, and payment from other sources	Non-conforming	Conforming

As discussed above, VDSCF's proposed payor mix is based on unsupported assumptions and VDSCF does not provide estimated payor mix for charity care and self-pay patients separately as required by Criterion 10-Demonstration Project. **VDSCF's application does not meet the requirements of Criterion 10-Demonstration Project. As such, VDSCF is comparatively inferior to SCDP of Greenville.**

Please note that SCDP of Greenville does not believe that the applicants in this review should be compared based on the percentage or number of patients by age group, with preference given to pediatric patients. The SHCC specifically rejected KSA's petition for a pediatric-only demonstration project and approved the need determination which clearly states preferences for open-access to all dental professionals and access to a wide range of patients (see the Basic Principle and Rationale for Criterion 2 and Criterion 10-Demonstration Project). There is simply no interpretation of the dental single specialty ambulatory surgical facility demonstration project that would result in a preference for pediatric patients over adults.

#	*Criterion*	*VDSCF*	*SCDP of Greenville*
11	The proposed facility shall demonstrate that it will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation. The performance standards in 10A NCAC 14C .2013 would not be applicable	Non-conforming	Conforming

As discussed above, VDSCF utilization assumptions are unsupported and unreasonable based upon inconsistent statements for the number of projected referrals from KSA.

VDSCF's application does not meet the requirements of Criterion 11-Demonstration Project. As such, VDSCF is comparatively inferior to SCDP of Greenville.

Documentation of Support

SCDP of Greenville is superior to VDSCF in terms of dental professional support. On page 112 of its application, SCDP of Greenville provides a list of 24 individual dental professionals that committed to performing at, or referring cases to, the facility. Additionally, four members of Triangle Implant Center committed to shifting patients to SCDP of Greenville. As such, SCDP of Greenville received support from 28 individuals committing volume to SCDP of Greenville. In addition, 58 letters of support from dental professionals were also included in SCDP of Greenville's application and numerous letters of support from community agencies, universities, and more.

In Exhibit 26 of its application, VDSCF provides a list of ten pediatric dentists in support of its project and a list of eight oral surgeons in support of the project for a total of 18 letters of support. Two additional organizations, Goshen and CommWell, provided letters of support in Exhibit 32 indicating the intention to refer cases to VDSCF. As noted in the Unsupported Methodology and Assumptions for Utilization section above, there are issues with VDSCF's assumptions regarding its dental professionals. Nonetheless, even if all of 20 supporting letters for VDSCF are included, SCDP of Greenville has superior support from the community.

Additionally, as evidenced in Attachments 3 and 4, VDSCF has clearly and intentionally misled individuals in the dental community in order to garner support for its projects. In an electronic communication sent to dental professionals across the state, Anuj James, a member of KSA and owner of the proposed VDSCR and VDSCF, states with emphasis that "[t]*he NC Dental Society has endorsed only our proposal, and the responsibility this caries* [sic] *is one we take very seriously*" (Attachment 3). **This statement is false.** The North Dental Society did not endorse Valleygate's proposals. When the NC Dental Society was made aware of this falsehood, the NC Dental Society and Valleygate sent electronic communications retracting the statement. Anuj James' email on May 13, 2016 states "[w]*e are writing to clarify a misstatement in that e-mail. While the North Carolina Dental Society supports the concept of a demonstration project for a single specialty dental ambulatory surgery center, they have not endorsed Valleygate's proposal. We apologize for the inaccuracy of our previous email*" (see Attachment 4). The North Carolina Dental Society's email on May 16, 2016 states "[w]*e just learned that one of the CON applicants, Valleygate Dental Surgery Centers, inaccurately claimed in emails variously dated May 10 and May 11 that the NCDS has endorsed its CON application. This is simply not the case, and we asked Valleygate Surgery Centers to stop making such a claim and issue a retraction to all of the recipients of its emails*" (see Attachment 5).

Given the record of VDSCR and VDSCF's owners, it is unclear whether any of the support for these projects is reliable, outside of its ownership and the existing members of KSA. As shown in Attachment 6, Virginia Jones emailed one dental professional and stated that the financials in the CON are not the "true numbers." It is possible that

VDSCR and VDSCF have misled other dental professionals in verbal conversations or other electronic communications that have not yet been discovered to be misleading, in order to garner support for their applications.

It is clear from the superior support of SCDP of Greenville, that its proposal is preferred by the dental professional community. As noted, above, VDSCF does not provide open access to dental professionals, as required by **Criterion 2-Demonstration Project**. By comparison, SCDP of Greenville provides open access to dental professionals and is seeking much broader ownership which has resulted in overwhelming support from dental professionals in the community.

VDSCF's misleading statements above may be an attempt to generate additional support in light of SCDP of Greenville's superior support. Please note that July 10, 2003 memorandum[3] from the CON Section Chief, *Regarding Letters of Support Submitted for Certificate of Need Applications*, is clear that an *"application cannot be amended with information contained in any letters or materials received during the written comment period or at the public hearing . . . Consequently, all information the applicant intends to rely on to demonstrate conformance of the application with the review criteria must be provided by the applicant in its application when first submitted to the agency."*

In summary, SCDP of Greenville is superior to VDSCF in terms of support.

Please note that the Agency has historically included support as a comparative factor as shown in Attachment 7 which includes an excerpt from the 2011 Wake County Acute Care Bed review.

Geographic Access

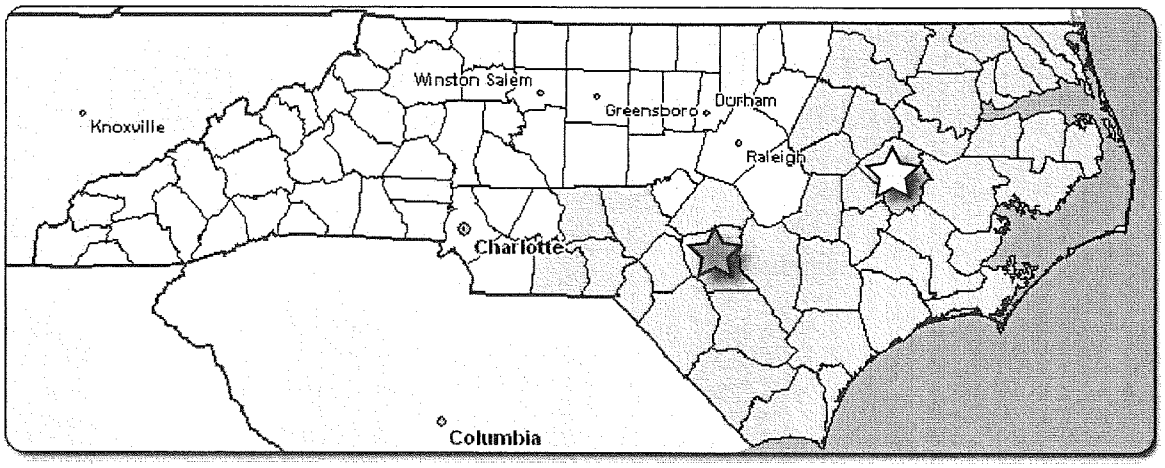
SCDP of Greenville proposes to locate its facility in Pitt County and VDSCF proposes to locate its facility in Cumberland County. SCDP of Greenville is the superior to VDSCF in terms of geographic access as discussed below.

As noted on pages 82-91 of its application, SCDP of Greenville believes its proposed location is the most effective alternative for a dental single specialty ambulatory surgical facility demonstration project in Region 3. SCDP of Greenville's proposed location is ideal for numerous reasons including the presence of hospitals in southern coastal and western regions that perform a significant volume of oral surgery. Further, given the geographic breadth of Region 3, it is important to locate the proposed facility in an area that is accessible by residents of the northeastern counties, such as Currituck, while also remaining accessible to residents of the southeastern counties. Pitt County is centrally located in Region 3 and is nearly equidistant from the "corner counties" of the

[3] https://www2.ncdhhs.gov/dhsr/coneed/support.html

region, Currituck County in the northeast, Anson County in the southwest, and Brunswick County in the south. Finally, SCDP of Greenville's location also provides proximate access to ECU's School of Dental Medicine for the training of students and residents which will expand the number of dentists trained in this unique setting across the state.

By comparison, VDSCF's location, in Cumberland County, will not provide proximate access to ECU's School of Dental Medicine. As shown in the map below, VDSCF's proposed facility is not centrally located in Region 3 and is closer to Region 1 and Region 2 where other dental single specialty ambulatory surgical facility demonstration projects may be developed.



In particular, VDSCF's location is inferior given the two dental single specialty ambulatory surgical facility demonstration projects for Region 1 propose to develop facilities in Wake County, VDSCR in Garner and SCDP of Raleigh in Raleigh. As shown in the table below, VDSCF will be located closer to both VDSCR and SCDP of Raleigh than SCDP of Greenville.

Distance in Miles Between Proposed Facilities

	VDSCR	*SCDP of Raleigh*
VDSCF	57 miles	72 miles
SCDP of Greenville	76 miles	83 miles

SCDP of Greenville believes that placing the Region 1 and Region 3 dental facilities further apart, particularly with greater access for the northeastern coastal areas of North Carolina, will provide the greatest geographic access for patients.

In summary, SCDP of Greenville is superior to VDSCF in terms of geographic access.

Quality of Care

VDSCF will utilize contract CRNAs under supervision of the dental anesthesiologists. By contrast, SCDP of Greenville will use only licensed anesthesiologists in the ASC rather than certified registered nurse anesthetists in order to ensure the highest level of quality, safety, and patient-centric care possible. Access to a licensed facility with board certified anesthesiologists increases the safety and efficiency of surgical cases requiring sedation.

VDSCF proposes to develop dental treatment suites. These rooms will be inherently less safe due to lack of an anesthesiologist. As VDSCF states on page 33, "[t]*he applicant will staff procedures in these rooms with a CRNA under the supervision of the performing dentist. Either the CRNA or dentist will be with all sedated patients in the treatment rooms, regardless of the level of sedation.*" Many light sedations start easily but can often become complicated with intra-operative issues. The inability to convert to a general anesthetic increases the risk and the lack of an anesthesiologist makes the sedation risks fall fully on a dentist who does not have the training of a medical anesthesiologist. By contrast, SCDP of Greenville will use only licensed anesthesiologists for all cases at its facility. As noted above, the North Carolina Board of Dental Examiners is addressing office-safety concerns as a reaction to two recent adult fatalities in North Carolina dental offices.

VDSCF proposes to develop two operating rooms, two procedure rooms, and one dental treatment suite, or five rooms in total. As shown in Table VII.7 of its application on pages 186-187, VDSCF pre-, post-, and operating room staff includes 1.2 FTE RNs and 1.1 surgical technicians or 2.3 FTEs in total excluding CRNAs. This results in a ratio of 0.46 FTEs per room (0.46 = 3.3 FTEs ÷ five rooms).

VDSCF Dental Case Staffing

	Pre-	*Post-*	*OR*	*Total*
RN	0.60	0.60		1.20
Surgical Technician			1.10	1.10
Total	0.60	0.60	1.10	2.30
# of Rooms				5
FTEs per Room				0.46

Source: VDSCF application pages 186-187.

By contrast, SCDP of Greenville proposes to develop two operating rooms and two procedure rooms, or four rooms in total.. As shown in Table VII.7 on page 176 of SCDP of Greenville's application, pre-, post-, and operating room staff includes 1.5 FTE RNs, 1.5 FTE Dental Assistant I and 2.0 FTE Dental Assistant II or 5.0 FTEs in total. This results in a ratio of 1.25 FTEs per room (5.0 FTEs ÷ four rooms).

SCDP of Greenville Dental Case Staffing

	Pre-	*Post-*	*OR*	*Total*
RN		0.50	1.00	1.50
Dental Assistant I	1.00	0.50		1.50
Dental Assistant II	0.50	0.50	1.00	2.00
Total	**1.50**	**1.50**	**2.00**	**5.00**
# of Rooms				**4**
FTEs per Room				**1.25**

Source: SCDP of Greenville application page 176.

Both VDSCF and SCDP of Greenville will permit the dental professionals performing cases to bring their own dental assistants to assist. Given the analysis presented above, SDCP of Greenville is superior to VDSCF by providing facility staff in each room which will ensure quality of care and efficiency of service. By contrast, VDSCF's staff will required to cover two to three rooms each. Of note, these differences in staffing also affect the comparability of SCDP of Greenville's and VDSCF's expenses per case.

In summary, SCDP of Greenville is superior to VDSCF in terms of quality of care based on its provision of board certified anesthesiologists, with documented support, overseeing all cases and adequate clinical staff to support the number of rooms and cases proposed.

Access for Health Professional Training Programs

The following table illustrates each applicant's support from clinical training programs based on letters of support from each program included in the submitted certificate of need applications.

	VDSCF	*SCDP of Greenville*
ECU School of Dental Medicine		Yes
UNC Department of Oral and Maxillofacial Radiology		Yes
UNC Department of Oral Pathology		Yes
3D Dentists		Yes
UNC-Pembroke	Yes	
DENTAC	Yes	
Miller-Motte College	Yes	
Total	**3**	**4**

Based on the letters of support provided in the applications, **SCDP of Greenville has one more letter of support from health professional training programs.**

Of note, however, none of the clinical training programs in support of VDSCF train dental professionals; they are not involved in the training of dental students, dental residents, or community dentists. VDSCF's support is limited to programs that train assistants and not the dental professionals performing the cases.

Access by Underserved Groups

The following table illustrates the projected percentage of total cases to be provided to Medicaid recipients in the second operating year, as reported in Section VI.14 of each application. Of note, neither applicant projects Medicare patients, as Medicare does not provide dental care coverage.

	VDSCF	*SCDP of Greenville*
Percent of Total Cases to be Performed on Medicaid Recipients	88.5%	63.9%
Percent of Under 21 Cases to be Performed on Medicaid Recipients	95.1%	36.9%
Percent of 21+ Cases to be Performed on Medicaid Recipients	19.9%	78.1%

Based on the data presented in the applications, **VDSCF projects a higher percentage of Medicaid patients for patients under 21 years of age and SCDP of Greenville projects a higher percentage of Medicaid patients for patients 21 years and older.**

As discussed above, VDSCF's proposed payor mix is based on unsupported assumptions. Further, statements made during the public comment period by VDSCF's Chief Operating Officer, Virginia Jones, indicate that the projected payor mix for the project are unreasonable. Specifically, Ms. Virginia Jones, COO of VDSCF, stated in her

email included in Attachment 6 that the financial projections were *"EXTREMELY conservative, assuming 95 percent Medicaid, 5% charity, and a very low reimbursement rate."* (emphasis in original). Ms. Jones continues by indicating that these numbers are not the actual numbers they have or expect by saying, *"If the center can make it with these numbers, then the true numbers we have and believe we can accomplish are easily met."* (emphasis added). These statements indicate that VDSCF has other "true" financial projections that would provide a different comparison to SCDP of Greenville's application. Based on these factors, the projected payor mix shown in the application cannot be used as a basis for comparison.

Revenues

The following table illustrates each applicant's projected total gross revenue per case in the second year of operation, Federal Fiscal Year 2019.

	VDSCF	*SCDP of Greenville*
Gross Revenue for Total Cases	$4,800,673	$5,319,033
Projected # of Cases	3,810	2,714
Average per Case	$1,260	$1,960

Based on the data presented in the applications, VDSCF projects lower gross revenue per case than SCDP of Greenville. However, VDSCF and SCDP of Greenville's gross revenue per case statistics are not comparable for multiple reasons as discussed below.

The following tables illustrate each applicant's projected total revenue (net patient revenue) per case in the second year of operation, Federal Fiscal Year 2019.

	VDSCF	*SCDP of Greenville*
Net Revenue and Other Revenue for Total Cases	$2,607,731	$3,286,914
Projected # of Cases	3,810	2,714
Average per Case	$684	$1,211

Based on the data presented in the applications, VDSCF projects lower total revenue per case than SCDP of Greenville. However, VDSCF and SCDP of Greenville's total revenue per case statistics are not comparable for multiple reasons, as detailed below.

First, VDSCF's gross revenue does not include anesthesia revenue, as noted in an assumption on page 217; Other Revenue, which is shown on the pro forma financial statements below net patient revenue, includes anesthesia. By comparison, SCDP of Greenville's gross revenue includes revenue from the bundled charge which includes anesthesia.

Second, VDSCF's pro forma statements do not include any gross revenues, net revenues, or expenses associated with crowns, X-rays, or panorex images, as noted above. By comparison, SCDP of Greenville's gross revenues, net revenues, and expenses include crowns (based on reimbursement for the supplies used by dental professionals), X-rays, and panorex images.

Third, statements made during the public comment period by VDSCF's Chief Operating Officer, Virginia Jones, indicate that the projected payor mix and revenues for the project are unreasonable. Specifically, Ms. Virginia Jones, COO of VDSCF, stated in her email included in Attachment 6 that the financial projections were *"EXTREMELY conservative, assuming 95 percent Medicaid, 5% charity, and a very low reimbursement rate."* (emphasis in original). Ms. Jones continues by indicating that these numbers are not the actual numbers they have or expect by saying, *"If the center can make it with these numbers, then the true numbers we have and believe we can accomplish are easily met."* (emphasis added). These statements indicate that VDSCF has other "true" financial projections that would provide a different comparison to SCDP of Greenville's application. Based on these factors, the projected revenues shown in the application cannot be used as a basis for comparison.

Of note, SCDP of Greenville's communications with Dr. Mark Casey, Dental Director of the NC Division of Medical Assistance have indicated a Medicaid reimbursement rate for the proposed dental surgery to be consistent with its assumed reimbursement of $736 per case. By contrast, VDSCF's application assumes Medicaid reimbursement to be $175 per case, which is unreasonably low, and provide no justification for that assumption as shown on page 242.

Finally, the differences in patient population between the two facilities makes a comparison unreasonable. As noted throughout these comments, VDSCF's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCF projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Greenville projects 34.5 percent. This difference in patient population results in differences in the revenues. The revenue (and expense) of restoring permanent teeth is greater than primary teeth (or "baby teeth") based on the instruments and supplies required. As such, a reasonable comparison cannot be made.

Expenses

The following table illustrates each applicant's projected total expenses per case in the second year of operation, Federal Fiscal Year 2019.

	VDSCF	*SCDP of Greenville*
Total Expenses for Total Cases	$2,227,293	$2,963,955
Projected # of Cases	3,810	2,714
Average per Case	$585	$1,092

Based on the data presented in the applications, VDSCF projects lower total expenses per case than SCDP of Greenville. However, VDSCF and SCDP of Greenville's total expenses per case statistics are not comparable for multiple reasons as discussed below.

First, VDSCF's pro forma statements do not include any expenses associated with crowns, X-rays, or panorex images, as noted above. By comparison, SCDP of Greenville's expenses include crowns, X-rays, and panorex images.

Second, statements made during the public comment period by VDSCF's Chief Operating Officer, Virginia Jones, indicate that the projected financial statements for the project are unreasonable.

Further, as noted above, VDSCF provides an inferior level of staffing for its rooms in comparison to SCDP of Greenville.

Finally, the differences in patient population between the two facilities makes a comparison unreasonable, particularly, for Medicaid. As noted throughout these comments, VDSCF's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCF projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Greenville projects 34.5 percent. This difference in patient population results in differences in the expenses. The revenue (and expense) of restoring permanent teeth is greater than primary teeth (or "baby teeth") based on the instruments and supplies required.

As such, a reasonable comparison cannot be made.

SUMMARY

As noted previously, SCDP of Greenville maintains that the VDSCF application cannot be approved as proposed. As such, SCDP of Greenville maintains that it has the only approvable applications based on its comments. Based on its comparative analysis, SCDP of Greenville believes that its application represents the most effective alternative for meeting the need identified in the *2016 SMFP* for a dental single specialty ambulatory surgical facility demonstration project in Region 3. As such, the Agency can and should approve SCDP of Greenville.

Attachment 1

CAPE FEAR VALLEY HEALTH

August 12, 2015

BEHAVIORAL HEALTH CARE
BLADEN COUNTY HOSPITAL
CAPE FEAR VALLEY MEDICAL CENTER
CAPE FEAR VALLEY REHABILITATION CENTER
HEALTH PAVILION HOKE
HEALTH PAVILION NORTH
HIGHSMITH-RAINEY SPECIALTY HOSPITAL

BLOOD DONOR CENTER
CANCER CENTER
CARELINK
CAPE FEAR VALLEY HOMECARE & HOSPICE, LLC
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
PRIMARY CARE PRACTICES
SLEEP CENTER

Sandra Greene, Ph.D., Chairman
North Carolina State Health Coordinating Council Acute Care Sub-Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Cape Fear Valley Health System Comments Regarding the Knowles, Smith and Associates, LLP (d/b/a Village Family Dental)

Dear Dr. Greene:

Cape Fear Valley Health System (CFVHS) appreciates the opportunity to comment on the Petition submitted by Knowles, Smith and Associates (d/b/a Village Family Dental) for an adjusted need determination in the 2016 SMFP for a specialty pediatric dental ambulatory surgical center in Cumberland County. While CFVHS understands the difficulties expressed by the Petitioners, CFVHS respectfully does not believe adding additional operating rooms in Cumberland County is the most effective health planning solution and does not support the changes requested by Village Family Dental for the following reasons.

1. A similar Petition was submitted in the Spring to add a new policy to allow the development of a specialty pediatric dental ambulatory surgical center in southeastern North Carolina. Comments submitted by CFVHS regarding that Petition remain relevant and are submitted here as Attachment 1. CFVHS has repeatedly offered available operating rooms to Village Family Dental. Village Family Dental has expanded care at one location only. Additional available operating room space is available.

2. During the Public Hearing process representatives of Village Family Dental stated that procedures currently done in the dental office will be done in the procedure rooms in the facility once developed. The fact that these procedures will now be eligible for an additional facility fee, increasing the cost of care for all those patients now treated in an ambulatory surgical facility instead of a dental office, needs to be part of the conversation regarding this Petition.

Thank you for the opportunity to comment.

Sincerely,

Sandy Godwin

Sandy Godwin
Executive Director of Corporate Planning
Cape Fear Valley Health System
P.O. Box 2000
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stgodwin@capefearvalley.com

CAPE FEAR VALLEY®
TRANSFORMING HEALTHCARE™

March 20, 2015

Sandra Greene, Ph.D., Chairman
North Carolina State Health Coordinating Council Acute Care Sub-Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Cape Fear Valley Health System Comments Regarding the Knowles, Smith and Associates, LLP (d/b/a Village Family Dental)

Dear Dr. Greene:

Cape Fear Valley Health System (CFVHS) appreciates the opportunity to comment on the Petition submitted by Knowles, Smith and Associates (d/b/a Village Family Dental) to add a new policy to allow the development of a specialty pediatric dental ambulatory surgical center in southeastern North Carolina. CFVHS does not support the changes requested by Village Family Dental for the following reasons.

1. <u>Misrepresentation of Available Capacity at Cape Fear Valley Health System Surgical Facilities</u>

On page 5 of its Petition, Village Family Dental states that dental operation room block time at Highsmith Rainey (HRSH) for pediatric dentists is limited to one block a week. This is incorrect. Village Family Dental currently has block time <u>every day</u> in one of the three operating rooms at HRSH Monday through Friday with the exception of two Mondays a month. Surgical time has not decreased; in fact, available surgical time for Village Family Dental within the CFVHS recently has been increased.

In FFY 2014, 2,094 surgical cases were performed at HRSH, of these 1,075 were oral surgery. Of these 706 were pediatric dental cases performed by Village Family Dental providers. This is far more than one day block time per week. In fact, utilizing a case time of 2.5 hours per case and 90% utilization of available Village Family Dental block time, as suggested in the Village Family Dental Petition, this case volume equates to one operating room annually operating at a rate exceeding 80% of capacity.

Village Family Dental Available Capacity at HRSH in FFY 2014

706 Cases x 2.5 Hrs per Case = 1,765 Hrs @ 90% (VFD target utilization) = 1.765/.9 = 1,961 Hrs
1,961 Surgical Hrs / 2,340 Hrs (SMFP OR Capacity) = 1 Operating Rooms at 83.8% of Capacity

Village Family Dental's statement on page 5 that dental surgery is restricted to the "older" operating rooms at HRSH implies that the facility is sub-standard and does not meet their surgical needs. In fact, the operating rooms at HRSH are accredited by The Joint Commission and have the same capabilities of all other shared operating rooms within the Cape Fear Valley Health System.

CFVHS considers Village Family Dental an important member of the Medical Staff and has worked with them to meet their surgical needs. In addition to providing expanded surgical hours, CFVHS has acquired specialty x-ray equipment for the pediatric dentists in the last several years.

2. **Cape Fear Valley Health System Increased Surgical Capacity**

On March 9, 2015, Cape Fear Valley Health System opened CFV Hoke Hospital in Raeford, North Carolina. The new hospital has two operating rooms, one of which was relocated from HRSH and one of which is new to the total CFVHS surgical inventory in Cumberland and Hoke Counties. In addition to their block times at HRSH, Village Dental currently has one day a week in one of the two operating rooms at CFV Hoke. CFV Hoke was developed to shift primary care, including appropriate surgical care, for residents of Hoke County out of CFVMC in Fayetteville to the community hospital setting. As Village Family Dental's utilization at CFV Hoke warrants, additional blocks can be arranged for them. Further, as surgical volumes shift from Fayetteville operating rooms to CFV Hoke, additional time also may be available at HRSH and potentially CFVMC.

In addition, CFVHS has available surgical capacity at both Harnett Health in Harnett County and CFV Bladen County Hospital in Bladen County. Harnett Health has seven operating rooms between Central Harnett Hospital in Lillington and Betsy Johnson Hospital in Dunn. CFV Bladen has two operating rooms in Elizabethtown. Both of these facilities are very accessible to residents of Cumberland, Robeson, Harnett, Hoke and Bladen Counties. Additional block time is available at these hospitals. At a minimum 40 hours of block time could be made available at either of these underutilized surgical facilities.

3. **Unnecessary Duplication Increasing the Operating Room Surplus in Southeastern North Carolina.**

In the 2015 SMFP, the three county area of Cumberland, Robeson and Hoke Counties had an operating room surplus of nearly 10 operating rooms. Both CFVHS and Southeastern Regional Medical Center are Medicaid Safety Net Providers. Both counties have significant Medicaid and uninsured populations and both providers meet the needs of all the population.

Cape Fear Valley Medical Center has long been recognized as the safety net provider for patients regardless of income or insurance in south central North Carolina. As the tertiary provider for south central North Carolina, Cape Fear Valley Medical Center has no barriers to care for the uninsured and the underinsured. The development of a freestanding pediatric dental ambulatory surgery facility would negatively impact the efficient operation of the surgical unit at HRSH and would negatively impact financial viability of CFVHS.

4. **Village Family Dental and Anesthesiologist**

Several times throughout the Petition, Village Family Dental references difficulties with anesthesiology providers. The SMFP is not the vehicle to address difficulties between the dentists and anesthesiologists. The SMFP addresses capacity issues with operating rooms. As discussed above CFVHS has worked with the dentists at Village Family Dental and believes that sufficient operating room capacity exists.

5. **CFVHS Recommendation**

There is sufficient operating room capacity in Cumberland, Robeson, Harnett, Hoke and Bladen Counties to meet the surgical needs of Village Family Dental. Therefore, there is no need for the proposed Policy.

Again, thank you for the opportunity to submit our concerns regarding the Knowles, Smith and Associates (d/b/a Village Family Dental) Petition.

Sincerely,

Sandy Godwin

Sandy Godwin
Executive Director of Corporate Planning
Cape Fear Valley Health System
P.O. Box 2000
Fayetteville, NC 28302-2000
stgodwin@capefearvalley.com

Attachment 2

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	March 30, 1999
FINDINGS DATE:	April 7, 1999
PROJECT ANALYST:	Mary M. Edwards
PROJECT I.D. NUMBER:	J-5938-98/Duke University/Develop a 14-bed cardiac surgery hospital in Lumberton by relocating 14 acute care beds and one heart lung bypass machine from Duke Medical Center to Southeastern Regional Medical Center/Robeson County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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, ambulatory surgical operating rooms, or home health offices that may be approved.

NC

Duke University Hospital (Duke), an acute care hospital located in Durham, proposes to establish a new facility in Lumberton to provide percutaneous transluminal coronary angioplasty (PTCA) and open heart surgery services. The facility will be known as the Duke Heart Hospital and, as stated on page of seven of the application, "*will be licensed to Duke University, staffed by Duke University physicians and staff, furnished and equipped by Duke University, and managed by administrators from Duke University Hospital.*" Duke proposes to lease the air rights from SRMC and locate the Duke Heart Hospital on the third floor of SRMC in new space it will construct. The line drawing for the facility includes two operating rooms, a six-bed intensive care unit, an eight-bed telemetry unit, exam rooms, offices, patient waiting areas, utility and storage space.

Duke asserts on page 52 of the application that "*This application proposes the relocation of part of Duke University's existing PTCA and open heart surgery*

equivalent cardiac catheterization procedures that would be needed to support an open-heart surgery program of the size proposed.

Further, the applicant failed to demonstrate that the proposed project would be consistent with the need determinations and the applicable policies in the 1998 State Medical Facilities Plan. See Criterion (1). The applicant failed to adequately demonstrate the need for the proposed project. See Criterion (3). The applicant failed to demonstrate that the needs of the populations presently served at Duke University Hospital and SRMC will be adequately met following completion of the proposed project. See Criterion 3(a). The applicant failed to demonstrate that the financial feasibility of the project is based on reasonable projections of costs and charges. The applicant also failed to demonstrate the availability of funds for the total capital and operating needs of the project. See Criterion (5). The applicant failed to demonstrate that the proposed project would not result in unnecessary duplication of existing health service capabilities. See Criteria 3(a) and (6). The applicant failed to demonstrate the availability of adequate health manpower and management personnel to provide the proposed services. See Criterion (7). The applicant failed to demonstrate that adequate arrangements have been made for the provision of necessary ancillary and support services. The applicant did not adequately demonstrate that SMRC would be able to provide the advanced support services, highly trained physicians and staff needed to make the heart program possible. See Criterion (8). The applicant failed to demonstrate that the cost of construction will not unduly increase the costs of providing health services. The applicant failed to demonstrate that the design of the facility meets state regulations. See Criterion (12). The applicant failed to demonstrate that Medicaid recipients would be served by the applicant's proposed services. See Criterion 13(c). Further, the applicant does not conform to all of the applicable Criteria and Standards for Intensive Care Services in 10 NCAC 3R .1200 and to all of the applicable Criteria and Standards for Open-Heart Surgery Services and Heart-Lung Bypass Machines in 10 NCAC 3R .1700. Therefore, Duke University Hospital did not adequately demonstrate that it proposed the least costly or most effective alternative for the provision of the proposed services and is not conforming with this criterion.

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

NC

Duke proposes to develop the Duke Heart Hospital on the third floor of SRMC in new space it will construct. The total capital expenditure of the project as proposed by the applicant is $14,551,407, of which $8,930,900 is for construction

costs and $5,591,757 is for equipment and furniture, consulting fees and other miscellaneous costs. However, this amount does not include the $10 million for the lease of the cardiac catheterization lab or the unknown amount of the lease for the air rights. The applicant states that $14,551,407 will be provided from accumulated reserves, but the funds to be used for the leases are not identified.

Further, based on the information provided in the application, the CON project analyst determined that if an open heart surgery program were needed, then at least one additional cardiac catheterization room would also be needed to provide the projected number of diagnostic equivalent cardiac catheterization procedures. See Criterion (8). However, the costs for an additional cardiac catheterization laboratory are not included in this application, although these costs are essential to the hospital achieving its projected utilization. Therefore, the applicant has not adequately demonstrated that the projected capital cost of the project is reasonable because it does not include all the cost components required to implement the project as it is proposed in the application.

In Section IX.1 of the application, start-up expenses for the project are listed as $14,911,754 and the initial operating expenses are listed as $1,290,007, for a total of $16,201,762. The source of the total working capital for the project is identified as the unrestricted cash of the proponent. However, in Appendix X.10, the applicant states the estimated start-up costs are $15,926,754, including $10,444,855 for construction costs, $4,106,552 for equipment and furnishings, $354,347 for recruitment of staff, $6,000 for staff training and $1,015,000 for physician support and moving costs. The applicant erroneously included the $14,551,407 for capital costs in its projected start-up costs. If the capital costs are subtracted from the total of $15,926,754, the difference is an amount of $1,375,347 for start-up costs in Appendix X.10. However, in Section IX.1, after the capital costs are subtracted from the total of $16,201,762, the remainder of $1,650,355 is assumed to be the amount for start-up costs, which is $275,008 more than reported in Appendix X.10. Therefore, the applicant provided inconsistent estimates of the projected start-up and initial operating expenses for the project.

Attachment VIII.6 contains a letter from W. Roger Akers, Chief Financial Officer for Duke University Hospital stating "*The purpose of this letter is to certify that Duke University Hospital has as much as $20 million in unrestricted and undesignated funds to finance the development and early operation of the proposed Duke Heart Hospital in Lumberton, North Carolina.*" However, the applicant included audited financial statements in Exhibit XI.4 from Duke University. Consequently, it appears the funding will be provided by Duke University, not Duke University Hospital. Therefore, in accordance with a N.C. Court of Appeals decision filed November 19, 1996, the applicant did not adequately demonstrate the availability of the particular source of funds to be used for the capital costs, start-up costs and initial expenses of the of the project.

Additionally, the applicant indicates that Duke will lease the cardiac catheterization laboratory from SRMC (Section II.1, page 11 and Appendix II.2). According to the proformas, Duke appears to be leasing the catheterization laboratory business for ten million dollars (Form B-1) and borrowing the money to pay for the lease (Form B-1a – Interest Expense). However, the applicant did not include this amount in the capital cost of the project or include documentation indicating the availability and commitment of funds to be used for the lease of the cardiac catheterization laboratory. Further, on page seven of the application, the applicant states that Duke will lease the space from SRMC for 99 years. However, in Appendix II.2 on page four of the letter setting forth the preliminary understanding between Duke University Medical Center and Southeastern Regional Medical Center, the term of the lease is set forth as at least fifty years. Because the applicant provided inconsistent information regarding the length of the lease, the applicant did not adequately document that the assumptions on which the proposed lease cost is based.

The applicant states in a preliminary understanding between Duke University Medical Center and Southeastern Regional Medical Center, located in Appendix II.2, that it will rent air rights appurtenant to the existing premises. However, no specific amount for the lease of the air space is included in the agreement and throughout the agreement the applicant states that the amount of the lease for air space will be negotiated. Therefore, the applicant has failed to demonstrate the amount of the lease for the air space is based on reasonable projections of costs.

Further, the applicant proposes to contract with SRMC for the provision of ancillary and support services. However, the applicant provides inconsistent information in the application regarding the ancillary and support services to be contracted. Therefore, although costs are included in the proformas for ancillary and support services, the applicant does not adequately demonstrate that these costs include all the services for which it proposes to contract. See Criterion (8) for discussion.

The applicant also failed to provide sufficient information to demonstrate the reasonableness of other projected costs and charges. In response to Section X.2, on page 96, which requests that the applicant provide the projected charges for the services under review, the applicant did not provide a response. Consequently, the applicant did not provide a list of charges for any procedures to be performed at Duke Heart Hospital in years one, two or three. Further, in the assumptions included in Appendix X.10 for the proformas, the applicant failed to include information about the assumptions used to project revenue. Also, although the applicant included Medicaid as a reimbursement source in the response to Section VI.12.(b), the applicant did not include any revenue from Medicaid in Forms B-1 or B-1a. Therefore, projected revenue is not reasonable given the assumptions in

Section VI of the application regarding Medicaid. In response to Section VII.1(a), which requests that the applicant complete Table VII indicating the total number and type of staff to be employed in the facility in the second year after completion of the project, Duke University did not provide a response. Further, the applicant did not provide sufficient assumptions regarding staffing in Section VII.1 and in the proformas. Additionally, the applicant provided inconsistent information regarding staffing. See Criteria (7) and (8) for discussion. Consequently, the applicant failed to demonstrate the reasonableness of staffing costs in the proformas

The applicant did not provide sufficient information in the application to compare projected costs and charges for cardiac patients to be served in Lumberton versus current costs and charges for patients in Durham. Additionally, the applicant did not provide an adequate financial analysis of the impact of the opening and operating of the Duke Heart Hospital on Duke University Medical Center's costs and charges. The applicant states in Section X.6(b), page 98, that "*For procedures as a whole, we see the impact as a wash: the increase in fixed costs per cardiac catheterization procedure will be offset by the savings realized by moving open heart surgery procedures to Lumberton.*" However, the applicant did not provide sufficient information to demonstrate that the project will not have a negative effect on total cost per day or total cost per procedure at Duke.

In summary, the applicant failed to adequately demonstrate the availability of funds for the capital and operating needs of the project. Further, the applicant failed to demonstrate that the financial feasibility of the proposed project is based on reasonable projections of costs and charges. Therefore, the application is nonconforming with this criterion.

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

NC

Duke University Hospital proposes to establish open-heart surgery services and PTCA services in Lumberton by relocating a heart-lung bypass machine and 14 acute care beds from Duke University Hospital to Southeastern Regional Medical Center. However, the applicant did not adequately demonstrate the need for the establishment of open-heart surgery services and PTCA in Robeson County. As stated by the applicant, the needs of the patients in the proposed five-county service area are currently being met at Duke University Hospital in Durham. The applicant also states that providing PTCA and open-heart surgery procedures at Duke in Durham is more efficient and less expensive than providing services in Lumberton. In fact, the proposed project results in a costly duplication of services provided at Duke, such as:

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
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NC = Nonconforming
NA = Not Applicable

DECISION DATE: March 28, 2008
FINDINGS DATE: April 2, 2008
PROJECT ANALYST: Helen E. Alexander
CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBER: F-7993-07 KND Development 50, L.L.C. d/b/a Kindred Hospital Charlotte/Develop a new 60-bed freestanding long term care hospital (LTCH) / Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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.

NA

The applicant, KND Development 50, L.L.C. d/b/a Kindred Hospital Charlotte ("Kindred Charlotte"), proposes to develop a new long term care hospital (LTCH) in Charlotte with 60 long term care hospital beds. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the *2007 State Medical Facilities Plan (SMFP)*. Specifically, there is no need methodology or need determination in the *2007 SMFP* for long term care hospital beds. There are also no policies in the *2007 SMFP* that are applicable to development of long term care hospital beds. Therefore, this criterion is not applicable.

(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

NA

(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.

NC

In Section II. 5., page 14, the applicant states the only alternative "to the current proposal is doing nothing." However, the applicant did not adequately demonstrate the need for a long term care hospital in Mecklenburg County. See Criteria (3) and (6) for discussion. The applicant also failed to include all capital costs for the proposed project and failed to demonstrate that the proposal is financially feasible. See Criterion (5). The applicant failed to identify adequate staff for the provision of all of the proposed services or provide evidence of available funds to contract for needed staff. See Criterion (7) for discussion. The applicant failed to demonstrate that the proposed services would be coordinated with the existing health care system. See Criterion (8) for discussion. Additionally, the applicant failed to demonstrate that the proposed design represents the most reasonable alternative for the proposed services to be provided. See Criterion (12) for discussion. Further, the applicant did not adequately demonstrate that the proposal would have a positive impact on the cost effectiveness and quality of the services proposed. See Criterion (18a) for discussion. Therefore, the applicant did not adequately demonstrate that the proposal is an effective alternative. Consequently, the application is nonconforming to this criterion and is disapproved.

(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.

NC

In Section VIII.1, page 65, the applicant projects that the total capital cost of the project will be $28,706,000, which includes $23,000,000 for the construction costs, $4,506,000 for fixed equipment purchase/lease, and $1,200,000 for financing costs. Further, in Section IX, page 70, the applicant states that there will be start up expenses of $1,413,867 and initial operating expenses of $5,190,208 for a total working capital requirement of $6,604,075. In Section VIII.3, page 66, and Appendix 12, the applicant states that the entire capital cost will be funded with the accumulated reserves of Kindred Healthcare, Inc., which is the owner of the applicant. Appendix 12 contains an October 9, 2007 letter signed by James J.

Novak, Executive Vice President, East Group, Hospital Division of Kindred Healthcare, Inc., which states

> *"As an officer of Kindred Healthcare, Inc., I hereby document that, upon receipt of the Certificate of Need and other required approvals, Kindred Healthcare, Inc. will provide necessary funds to KND Development 50, LLC for the development of Kindred Hospital Charlotte. The audited financial statements included in this Certificate of Need application demonstrate the availability of financial resources to fund this hospital development project."*

However, the letter quoted above does not include documentation of the specific amount of funds committed to the project, or the authority of Mr. Novak to commit the funds for Kindred Healthcare Inc. Thus, the letter from Mr. Novak does not adequately demonstrate Kindred Healthcare, Inc.' s commitment of $28,706,000 for capital costs and $6,604,075 for working capital needs.

Further, the applicant failed to include all of the capital costs for the project in its projections in Section VIII. 1. For example, in Section IV. 4. (c), page 47, the applicant states

> *"Kindred will purchase a CT scan similar to the units currently in operation a*[t] *many of Kindred's other facilities."*

Appendix 2 contains a list of equipment to be acquired for the facility that costs over $10,000. However, a CT scanner is not on the list. Thus, the applicant did not adequately demonstrate the cost of the CT scanner is included in the projected capital expenditure for the project. Additionally, in Section III., page 44, the applicant provides a chart listing the services to be provided by the LTCH, which includes telemetry monitoring, dialysis, and laboratory services. In Section II., page 11, the applicant also lists services to be provided to patients at Kindred' s long term hospitals, which include inpatient hemodialysis. However, the list of equipment in Appendix 2 does not include any hemodialysis equipment or standard laboratory equipment. Thus, it is not apparent that costs for this equipment have been included in the projected capital expenditure for the project. Also, Appendix 11 states the construction estimate excludes a payment and performance bond, Builder' s Risk Insurance, and impact/utility service provider fees. It is not apparent that these costs have been included in the applicant' s projections of miscellaneous costs in Section VIII. 1. Therefore, the applicant failed to demonstrate the projected capital costs for the project are reasonable and did not include all costs of the project. Consequently, the applicant did not identify the source of funds to be used for the additional capital expenses to be incurred for the project.

In Appendix 13, Form B1-a: Projected Income, page 184, the applicant lists the proposed weighted revenues per patient day , which are $4,000 for Year One, $4,200 for Year Two, and $4,410 for Year Three following completion of the project. However, in response to Section X. 2., the applicant fails to state the proposed charge per patient day for either the long term care hospital beds or the ICU beds. In Section X.1 (b), page 71, Kindred fails to state whether the projected charges include all miscellaneous, ancillary, and professional fees. Furthermore, the applicant failed to differentiate between the revenue for the proposed 50 medical/surgical long term care beds as opposed to the ten ICU beds, as required by the instructions for Proforma B-1a.

Pro Forma B-1 for operating Years 1-3 shows projected net revenues will exceed net expenses in the second and third operating years, as illustrated in the table below.

Pro Forma Statement of Operating Results

Facility Profit/Loss	Year 1 (April 2011-March 2012)	Year 2 (April 2012-March 2013)	Year 3 (April 2013-March 2014)
Net Revenue	$5,207,951	$14,618,380	$21,784,368
Net Expenses	$9,978,857	$13,986,855	$17,555,769
Gross Profit/Loss	($4,770,906)	$631,526	$4,228,600
# of Patient Days*	5,468	12,045	16,472

*In its ProFormas, the applicant used the number of patient days to project revenues.

However, the above expenses do not include all direct and indirect costs. Specifically, Section X. 8., page 73, the applicant projects direct and indirect costs for the first three years as shown in the following table.

Expense	Year 1	Year 2	Year 3
Total Operating Expenses	$9,978,857	$13,986,855	$17,555,769
Land Lease	$302,886	$311,973	$321,332
Management	$200,000	$295,692	$439,292
Other Fixed	$139,284	$94,713	$96,607
Interest	$2,145,468	$2,145,468	$2,145,468
Depreciation	1,278,714	$1,278,714	$1,283,000
Total Expense	$14,045,209	$18,113,415	$21,841,468
Net Revenue	**$5,207,951**	**$14,618,380**	**$21,784,368**
Gross Profit/Loss	**($8,837,258)**	**($3,495,035)**	**($57,100)**

Thus, the ProForma Statement Projected Results from Operations on page 183 does not include any expenses for a land lease, management, other fixed expenses, interest, or depreciation. When expenses for these items are added to the ProForma Statements of Operating Results, expenses exceed revenue in all three years of operation following completion of the project. Consequently, the project as proposed is not financially feasible.

In addition, the Proforma operating expense statements do not include sufficient expenses for all necessary staff salaries and benefits. See Criterion (7) for discussion. Additionally, the applicant's projections of the number of patient days to be provided are unsupported and unreliable. Consequently, the costs and revenues that are based on these projections are also unsupported and unreliable. See Criterion (3) for discussion.

In summary, the applicant failed to adequately demonstrate the availability of funds for all capital needs of the project and did not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and revenues. Consequently, the application is not conforming to this criterion.

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

NC

The applicant failed to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, the applicant did not adequately demonstrate that the proposal would not result in unnecessary duplication of existing health service capabilities or facilities. Therefore, the application is not conforming to this criterion.

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

NC

In Appendix 6, page 114, the applicant provides the projected staffing for Kindred Hospital Charlotte for the pre-opening and the first three operating years. The applicant projects to employ a total of 25.3 full-time equivalent (FTE) positions for pre-opening, 60.5 FTE positions in Year One, 102.9 FTE positions in Year Two and 132.0 FTE positions in Year Three. The following table demonstrates the applicant's proposed FTE positions and the applicant's salary range as stated in Appendix 6:

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: September 22, 2009
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Helen E. Alexander

PROJECT I.D. NUMBERS: P-8326-09 / Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging / Acquire a fixed MRI scanner for an existing facility / Onslow County

P-8332-09 / Onslow MRI, LLC / Develop a new diagnostic center and acquire one fixed MRI scanner / Onslow County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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.

NC
Both Applicants

The 2009 State Medical Facilities Plan [SMFP] provides a methodology for determining the need for additional fixed Magnetic Resonance Imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2009 SMFP identified a need for one fixed MRI scanner in Onslow County. Two applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Onslow County. Although, the applications propose to develop a total of two fixed MRI scanners for Onslow County, only one may be approved. Each proposal is briefly described below.

Jacksonville Diagnostic Imaging, LLC (JDI) d/b/a Coastal Diagnostic Imaging (CDI) is a limited liability company with Triad Imaging, LLC as the sole member

OMLLC. In Section III, pages 65-68 of the application, the applicant describes the following alternative solutions that were considered: 1) maintain the status quo; 2) develop the proposed facility at a different geographical location in Onslow County; 3) contract with a mobile MRI provider; and 4) acquire a different scanner. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (18a) and Criteria and Standards for Magnetic Resonance Imaging Scanners in 10A NCAC 14C .2700. Therefore, the applicant did not adequately demonstrate that its proposal is an effective alternative and the application is nonconforming with this criterion.

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

NC
Both Applicants

CDI. In Section VIII, page 115 of the application, the applicant projects the capital cost for the proposed fixed MRI scanner. The following table summarizes the projected capital cost as stated in Section VIII, page 115 of the application.

CDI Projected Capital Cost **Table 16**

Description	*Cost*
Construction Contract/Labor	*$380,480*
Fixed Equipment Purchase/Lease	*$1,323,651*
Furniture	*$10,000*
Consultant Fees:	
➢ *Architect & Engineering*	*$15,000*
Contingency	*$50,000*
Total	*$1,779,132*

Note: Includes cost of MRI scanner, MRI injector, 7% sales tax on both, rigging, shipping and insurance. MRI quote includes chiller and application training.

In Section IX, page 122, as an existing facility, the applicant projects no start-up or initial operating cost associated with the proposed project. See Attachment 29 for a detailed vendor's quote and Attachment 30 for a list of projected capital cost for the purchase of CDI's proposed fixed MRI scanner. In Section VIII, 2, (c), page 114 of the application, the applicant states, *"The straight line method of depreciation will be used."* In Section VIII.3, page 116, CDI indicates that the proposed project with be financed by Accumulated Reserves of Novant Health, Inc. Attachment 32 contains funding letters. The first letter dated April 6, 2009 from Dean Swindle, President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., states:

"As the President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., I have the authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by MedQuest, an affiliate of Novant Health, Inc. Novant Health, Inc. is the not-for-profit parent company of MedQuest. ...

I can and will commit Novant's reserves to cover all the capital costs associated with the project, including the project capital cost of $1,799,132."

The second letter, dated March 30, 2009 from Dean Swindle, President Ambulatory Services and Chief Financial Officer, Novant Health, Inc., states:

"Please allow this letter to confirm the availability of funds of MedQuest, Inc. through Novant Health Inc.'s $425 million Revolving Line of Credit. As of December 31, 2008, MedQuest, Inc. had in excess of $12.6 million of availability under this Revolving Line of Credit. I commit that Novant Health, Inc. will furnish to MedQuest, Inc. all funds that are needed from the Revolving Line of Credit so that MedQuest, Inc. can undertake the project described ..."

The final funding letter, dated April 10, 2009 from Edward Williams, Chief Accounting Officer MedQuest Associates which states:

"This letter confirms the availability of funds for Jacksonville Diagnostic Imaging, LLC, d/b/a Coastal Diagnostic Imaging ("CDI") to support the capital expenditure required for the acquisition of the fixed MRI that CDI proposes. The cost of the proposed fixed MR system in CDI's Certificate of Need is $1,279,042 including tax. The total capital expenditure required for the proposed project is $1,779,132, which includes the cost of the MR system and other related equipment, and common consulting fees.

Triad Imaging, Inc. is the sole member of Jacksonville Diagnostic Imaging, LLC. MedQuest, Inc. is the sole member of Triad Imaging, Inc. MedQuest will make available all funds necessary to finance the proposed project and required working capital, as well [sic] *any unforeseen expenses related to the CON application, through its accumulated reserves and through MedQuest Inc.'s $425 million resolving Line of Credit with Novant Health, Inc. ..."*

Attachment 33 of the application contains *Novant Health, Inc. and Affiliates combined Financial Statements as of December 31, 2007 and 2006.* According to the financial statements, Novant had $321,913,000 in cash and cash equivalents as of December 31, 2007. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

Additionally, in Section VIII.3, page 116, CDI indicates that the proposed project with be financed by Accumulated Reserves of Novant Health, Inc. However, in Attachment 32, a letter from Dean Swindle, President Ambulatory Services and Chief Financial Officer Novant Health, Inc., it states, *"I commit that Novant Health, Inc. will furnish to MedQuest, Inc. all funds that are needed from the Revolving Line of Credit so that MedQuest, Inc. can undertake the project described ..."* Further, Attachment 32 also contains a letter from Edward Williams, Chief Accounting Officer MedQuest Associates which states, *"MedQuest will make available all funds necessary to finance the proposed project and required working capital ... through its accumulated reserves and through MedQuest Inc.'s $425 million resolving Line of Credit with Novant Health, Inc. ..."*

In the financial pro formas for Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging, pages 133-143 of the application, the applicant projects CDI's average gross, net revenue, and average net revenue per patient for the first three operating years as illustrated in the table below. See Pro Forma Tab.

Projected Gross and Net Revenue for Proposed MRI Services **Table 17**

Year	# Of Patients	Budgeted Gross Revenue	Net Revenue	Average Net Revenue Per Patient	Net Income
Interim Full FY 07/01/09-6/30/10	5,275	$10,694,817	$3,056,278	$579.39	$1,228,821
FY 1 (7/10-6/11)	6,522	$13,223,561	$3,778,922	$579.41	$1,239,766
FY 2 (7/11-6/12)	7,304	$14,810,388	$4,232,392	$579.46	$1,504,020
FY 3 (7/12-6/13)	7,889	$15,995,219	$4,570,984	$579.41	$1,807,649

As illustrated in the table above, the applicant's average net revenue per patient will stay consistent for the first three years of operations following the proposed project. The applicant projects that the proposed project will show a profit during its first three years of operations.

The applicant does not differentiate as to how much of the proposed project will be financed by MedQuest's accumulated reserves or through Novant Health, Inc., resolving Line of Credit. Nor does the applicant provide the rate of interest to be paid on the revolving Line of Credit. The applicant accounts for some interest expenses on the line of credit to be paid in the pro formas. Further, in the pro forma section, *"Expenses Calculation Basis"* it states, *"Interest Expenses based on LOC agreement with applicant's ultimate parent company."* However, as the applicant did not provided a copy of the agreement, it is unclear as to how much of the proposed capital cost will be paid through Novant's revolving Line of Credit and the interest rate to be paid. Therefore, it is impossible to determine if the applicant has accounted for all related expenses.

Furthermore, the applicant is asked in Section X.2, (a), page 124 of the application to, *"Provide a Balance Sheet for the entire facility for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's cash flow projections are reasonable.

Additionally, the applicant is asked in Section X.2, (b), page 124 of the application to, *"Provide a Statement of Revenues and Expenses for the entire facility for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's projected revenues and expenses are reasonable.

Further, the applicant is asked in Section X.2, (c), page 125 of the application to, *"Provide a Statement of Revenues and Expenses for each Service Component included in the Proposed Project for the last full fiscal year immediately prior to submission of the application."* However, CDI did not provide the requested information. Thus, it can not be determined if the applicant's projected revenues and expenses for the proposed MRI services are reasonable.

In Section II, page 34 of the application, the applicant provides the projected charges for the top 20 MRI procedures for the first three years following completion of the proposed project. The Applicant states the following in Section II, page 33:

> *"CDI will bill patients for the MRI diagnostic studies performed... CDI has not assumed any inflation in its charges during the first three years of operation following implementation. These are global charges, which include both the technical component and the radiologist's professional fee. CDI will pay the radiologists, which is reflected in the expenses for the proposed project."*

However, CDI does not include the charges for its professional fees in its *Statement of Revenues and Expenses* in the Pro Formas. The project analyst calculates the projected professional fee based on the lowest fee reported in Section II, page 34 for the first three years of services following project completion as illustrated in the table below.

Projected Professional Fee **Table 18**

Year	Radiologist Professional Fee	Projected Number of Procedures	Minimum Total of Professional Fees
FY 1 (7/10-6/11)	$212	6,522	$1,382,664
FY 2 (7/11-6/12)	$212	7,304	$1,548,448
FY 3 (7/12-6/13)	$212	7,889	$1,672,468

As illustrated in the above table, project analyst calculates the projected professional fees for FY1 through FY3 based on the number of procedures the applicant projects to perform from FY1 through FY3, as reported in the Pro forma Section of the applicant, and by the lowest professional fee (MRA Head without contrast) reported by the applicant. Thus, at minimum, the applicant failed to include in its Pro forma professional fees totaling at least $1,382,664 in FY1, $1,548,448 in FY2, and $1,672,468 in FY3. Thus, in all three operating years, addition of the minimal professional fee reported by the applicant will result in a loss as shown below.

Net Income and Projected Professional Fee FY1- FY3
Table 19

Year	Net Income	Professional fee	Loss
Yr 1	$1,239,766	$1,382,666	(-$142,900)
Yr 2	$1,504,020	$1,548,448	(-$44,428)
Yr 3	$1,807,649	$1,672,468	$135,181

The applicant's stated professional fee for the twenty top MRI procedures on page 34 of the application, range from $212.00 to $454.00. Thus, the expenses for the professional fee are likely to be greater than shown above.

Therefore, expense projections proposed by CDI are understated because no expense is included for the professional fee. Therefore, the applicant's expense projections are unreasonable and unreliable.

In the Pro Forma, form B, the applicant projects the following direct/indirect expenses associated with the proposed fixed MRI as illustrated in the table below.

Average Procedure Cost **Table 20**

Year	FY1 7/10-6/11	FY2 7/11-6/12	FY3 7/12-6/13
Charge for MRI	$2,027.63	$2,027.63	$2,027.63
Total Projected Net Revenue	$3,778,922	$4,232,392	$4,570,984
Total Projected Expenses	$2,539,155	$2,728,372	$2,763,334
CDI Projected # of MRI Procedures	6,522	7,304	7,889
Total average cost/procedure	$389.32	$373.54	$350.28

In the illustrated table above, the project analyst projects the total average cost per procedure based on the total projected expenses and the projected number of procedures for FY2010 through FY2012 (expenses/procedures=average cost per procedure). As illustrated above, the average cost per procedure is projected to decrease during the first three years of operations following the completion of the proposed project. In FY1 the total average cost is projected at $389.32 with a $15.78 or 4.05% decrease by 2011 for a total average cost of $373.54. By FY2012 the total average cost is projected at $350.28 which reflects a $23.26 or 6.2% decrease in the cost. However, as the applicant did not provide the historical direct/indirect expenses for the facility, it can not be determined if the applicant's projected expenses are reasonable.

Furthermore, in Section VI, page 101 of the application, the applicant provides CDI's payor mix for Year 2. The project analyst calculated CDI's contractual allowance based on its projected payor mix and its Pro forma as illustrated in the tables below.

Year 2 07/01/2011-06/30/012 Payor Source and Contractual Allowance **Table 21**

Year 2011	Projected Number of Procedures 7,304			
Payor Source	**Percent**	**Procedures Total***	**Contractual Allowance Total Pro forma**	**Pro Forma # of Procedures**
Self Pay/Indigent/Charity	4.5%	328.68	$548,959	299
Medicare/Medicare Managed Care	18.2%	1,329.33	$1,903,496	1,193
Medicaid	7.7%	562.41	$860,005	567
Commercial Insurance	5.2%	379.81		299
Managed Care	62.0%	4,528.48		1,590
Other	2.5%	182.6	$6,961,923	3,356
Total	100%	7,311.31	$10,274,383	7,304

* Calculated by project analyst

In the table below, the project analyst calculated the contractual allowance based on Pro forma data times the number of procedures calculated by the percentages listed on page 101 of the application.

Year 2 07/01/2011-06/30/012 Contractual Allowance Table 22

Year 2011 Projected Number of Procedures 7,304			
Payor Source	**Pro Forma # of Procedures**	**Per Procedures**	**Contractual Allowance**
Self Pay/Indigent/Charity	299	$1,835.98	$548,959.00
Medicare/Medicare Managed Care	1,193	$1,595.55	$1,903,496.00
Medicaid	567	$1,516.76	$860,005.00
Commercial Insurance	299	$2,016.78	$603,016.36
Managed Care	1,590	$2,016.78	$3,206,675.62
Other	3,356	$2,016.78	$6,768,304.02
Total	7,304		$13,890,456.00

As illustrated in the table above, based on the number of procedures reported by CDI in its Pro forma, the contractual allowance differs from that projected by the applicant. In Table 22, the contractual allowance totals $10,274,383, however, based on the number of procedures projected to be performed by the applicant in the Pro forma, the contractual allowance is calculated to be $13,890,456.00. This is a difference of $3,616,073.00 [13,890,456.00-10,274,383= 3,616,073.00]. Therefore, CDI under estimates its contractual allowance by over 3 million dollars. Thus, any revenues based on those projections are overstated and unreliable.

In the *projected revenue and expense statement* provided in Form B-2 of the Pro Forma section, the applicant projects that revenues will exceed operating costs in each of the first three years of operation. The applicant provides the assumptions used to project revenue and expenses in the pro forma tab. However, the applicant projected number of MRI procedures to be performed in each of the first three operating years is unreasonable. Consequently, costs and revenues which are based on the number of procedures to be performed are also unreliable and unsupported. See Criterion (3) for discussion. Furthermore, expenses are understated because no professional fee expenses are included in the Pro forma statement of revenue and expenses. Thus, cost and revenues are unreliable and unsupported.

In summary, the applicants failed to adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenue. Therefore, the application is not conforming to this criterion.

OMLLC. In Section VIII, page 102 of the application, the applicant projects the capital cost for the proposed fixed MRI scanner. The following table summarizes the projected capital cost as stated in Section VIII, page 102 of the application.

OMLLC Projected Capital Cost **Table 21**

Description	*Cost*
Sub-Total Cost of Materials	*$133,200*
Cost of Labor	*$162,800*
Other(Design/construction contingencies)	*$59,200*
Sub-Total Construction Contract	*$355,200*
Fixed Equipment Purchase/Lease	*$1,996,706*
Movable Equipment Purchase/Lease	*$55,646*
Equipment and Furniture	*$5,000*
Consultant Fees:	
➢ *Architect & Engineering*	*$28,000*
➢ *Admin. and Legal Fees*	*$45,000*
Financing Costs (bond, load [sic]*)*	*$25,000*
Interest During Construction	*$10,656*
Sub-Total Miscellaneous	*$2,166,008*
Total Capital Cost of Project	*$2,521,208*

See Exhibit 5 for a detailed vendor's quote which states, *"Freight charges and taxes, if any, are payable upon receipt ... "*. Further in the *Terns and Conditions of Sale* item number *3. Taxes,* in the vendor's quote section, Exhibit 5 it states:

> *"Any sales, use or manufacturer's tax which may be imposed upon the sale or use of Products, or any property tax levied after readiness to ship, or any excise tax, license or similar fee required under this transaction, shall be in addition to the quoted prices and shall be paid by the purchaser* [emphasis added]."

However, the applicant failed to include the taxes and freight charges as a part of OMLLC's expenses. The project analyst calculates the projected taxes as illustrated in the table below based on the MRI scanner options located in Section VIII, page 103 of the application and the Vendor's Extended Quote in Exhibit 5.

OMLLC Projected Tax **Table 22**

Description	Cost
Vendor's Quote Extended Total	$1,615,956
MRI Scanner Options:	
➢ 1 7-channel breast coil	$85,000
➢ 1 iPat extensions	$25,000
➢ 1 SWI #Tim	$25,000
➢ 1 8-channel knee coil #Av, Es	$60,000
➢ 1 8-channel foot/ankle coil #Es	$63,000
➢ 1 8-channel wrist coil Tim	$55,000
➢ 1 Flow Quantification #Av	$20,000
➢ 1 Argus flow /MRC #MR	$15,000
➢ 1 Argus 4D Ventr.Function syngo	$27,000
➢ 1 Initial onsite training 12hrs	$3,250
➢ 1 Additional onsite training 6 hrs	$2,500
Total Scanner Options	$380,750
Total	$1,996,706
Projected Taxes @ 6.5%	$129,786
Total Price Including Projected Tax	$2,126,492

Note: Tax total rounded up from #126,785.89

As illustrated in the above table, the projected sales tax of 6.5% based on the extended Vendor's Quote and the selected options would total $129,786. Therefore, the projected total for the MRI scanner and selected options including tax is $2,126,492. Thus, the applicant did not included in its projected capital cost nor its Pro Formas the required taxes and fees associated with the proposed MRI scanner. Furthermore, the freight cost for the projected equipment could not be calculated as the Vendor nor the applicant provided the charges associated with the freight cost. The freight cost is normally determined, according to Business Dictionary by, *"Total-cost incurred in moving goods (by whatever means). It includes packing, palletizing, documentation and loading unloading charges, transport (carriage) costs, and marine insurance costs."* [3] Consequently, the projected capital cost would increase with the inclusion of the sales tax as illustrated below:

[3] Business Dictionary.com

OMLLC adjusted Projected Capital Cost
Table 23

Description	Cost
Sub-Total Construction Contract	$355,200
Fixed/Movable Equipment Purchase/Lease	$2,057,352
*Sales Tax @6.5%.	$133,728
Total equipment including tax	$2,191,080
Consultant Fees:	
➢ Architect & Engineering	$28,000
➢ Admin. and Legal Fees	$45,000
Financing Costs (bond, loan)	$25,000
Interest During Construction	$10,656
Total Cost Consultant Fees/ Financing Cost/Interest	$108,656
Total Capital Cost of Project (excluding freight charges)	$2,654,936

Note: *Sales tax rounded up to nearest dollar amount

As noted in the table above, the projected capital cost for the proposed projected, excluding freight cost, is $2,654,4936. However, OMLLC projects in Section VIII and in the Pro forma that the projected capital cost for the proposed project is $2,521,208. Thus, the applicant failed to demonstrate that it projected capital cost are reasonable and reliable.

In Section VIII, 2, (c), page 104 of the application, the applicant states, *"OMLLC uses straight line depreciation over a five-year useful life."* In Section VIII.3, page 105, OMLLC indicates that the proposed project with be financed by conventional loans. Exhibit 15 contains a funding letter from William P. Franklin, Jr., Senior Vice President, First Citizens Bank, dated April 3, 2009. The letter states:

> *"First-Citizens Bank & Trust Company ("First Citizens Bank") has been contacted by Onslow MRI, LLC ("Onslow MRI") in regards to its application ... It is our understanding that as part of its application, Onslow MRI is obligated to demonstrate the availability of funds for the capital and working capital needs as part of its proposal. In this regard, Onslow MRI has requested that First Citizens Bank consider providing financing for the Project on the following general terms:*
>
> *Loan Amount:* *$2,052,352*
> *Purpose of Loan:* *Purchase of MRI*
> *Type of Loan:* *Term loan – fully amortizing*
> *Term:* *7 years*
> *Interest rate:* *LIBOR plus 1.5% (with a 4.00% floor)*
> *Repayment Terms:* *Monthly payment of principal and interest*

Loan Amount:	*$383,200*
Purpose of Loan:	*Leasehold improvements*
Type of Loan:	*Term loan – not fully amortizing*
Term:	*5 years*
Interest rate:	*LIBOR plus 1.5% (with a 4.00% floor)*
Repayment Terms:	*Monthly payment of principal and interest ... with a balloon payment due at maturity.*

First Citizens Bank has conducted a preliminary review of the financial condition of Onslow MRI (which consisted almost exclusively of a preliminary review of its two members, Eastern Radiologist, Inc., and Costal Radiology Associates, PLLC), and based upon this review, we are willing to consider providing financing for the Project. "

As noted in the letter from First Citizens Bank, the loan amount for the proposed project is $2,052,352 for the MRI equipment and $383,200 for Leasehold improvements which total $2,435,552. Additionally, the total capital cost of the project ($2,654,611) exceeds the funding to be provided for the capital costs ($2,435,552). Therefore, the applicant failed to demonstrate funds for the capital cost of the proposed project.

In Section IX, page 109 of the application, the applicant projects the start-up cost to be $50,000, initial operating cost associated with the proposed project to be $100,000, with the total working capital for the start-up and initial operating expenses to be $150,000. The applicant further states on page 109 that the projected expenses to be covered are as follows:

"OMLLC is projecting start-up expenses related to the facility opening, equipment testing, staff training and supply inventory. OMLLC assumes rent and utilities, four weeks of staff training and management agreement, a physicist consultation for equipment setup, off-site application training for a physician, and two weeks of on-hand medical supply inventory prior to offering of services."

In Section IX, page 109, the applicant indicates that the start-up and initial operating expenses will be financed through a commercial loan. See Exhibit 15 for a letter from William P. Franklin, Jr., Senior Vice President, First Citizens Bank, dated April 3, 2009 which states:

" ... Onslow MRI has requested that First Citizens Bank consider providing financing for the Project on the following general terms:

Loan Amount:	*$250,000*
Purpose of Loan:	*Working capital for start-up and operating expenses*

Type of Loan:	*Term loan – interest only with principal due at maturity*
Term:	*1 year*
Interest rate:	*LIBOR plus 1.5% (with a 4.00% floor)*
Repayment Terms:	*Monthly interest ... interest and principal due at maturity."*

As noted on page 109 of the application, the applicant projects that the initial start-up and working capital of the proposed project totals $150,000. First Citizens Bank is considering providing financing of $250,000 for the initial start-up and working capital of the project. Even with the addition of the extra $100,000 [250,000-150,000=100,000], the applicant failed to demonstrate adequate provision of working capital for $51,988 in CY2011, the net operating loss shown in Pro forma B *Statement of Revenue and Expenses* as illustrated in the table below.

Net Operating Income Loss **Table 24**

Year	CY1 2011
Total Projected Revenue	$1,273,574
Total Projected Expenses	$1,325,562
Projected Operating Loss	$51,988

In summary, the applicant did not adequately demonstrate the availability of funds for the capital and operating needs of the project.

In the financial Pro formas for Onslow MRI, LLC, Section XIII, page 127 of the application, the applicant states OMLLC's projected average charge of $1,135.00 will remain consistent during the first three years of the proposed project.

In Section II, page 24 of the application, the applicant provides the projected charges for the top 20 MRI procedures for the first three years following completion of the proposed project. The Applicant states in Section II, page that, *"The radiologists will bill patients directly for professional services."*

In the *projected revenue and expense statement* provided in Form B-2 of the Pro Forma section, the applicant projects that revenues will not exceed operating costs during the first year of service for the proposed project. The applicant projects that during year two and three revenues will exceed the operating cost. The applicant provides the assumptions used to project revenue and expenses in the pro forma tab. However, the applicant's projections of the number of MRI procedures to be performed in each of the first three operating years are not based on reasonable assumptions and methodology.

In the Pro Forma, form B, the applicant projects the following direct/indirect expenses associated with the proposed fixed MRI as illustrated in the table below.

Average Procedure Cost Table 25

Year	CY1 2011	CY2 2012	CY3 2013
Charge for MRI	$1,135.00	$1,135.00	$1,135.00
Total Projected Net Revenue	$1,273,574	$1,807,218	$2,095,903
Total Projected Expenses	$1,325,562	$1,571,794	$1,641,754
OMLLC Projected # of MRI Procedures	2,093	3,018	3,558
Total average cost/procedure	$633.33	$520.81	$461.43

In the illustrated table above, the project analyst projects the total average cost per procedure based on the total projected expenses and the projected number of procedures for CY2011 through CY2013 (expenses/procedures=average cost per procedure). As illustrated above, the average cost per procedure is projected to decrease during the first three years of operations following the completion of the proposed project. In CY1 the total average cost is projected at $633.33 with a $112.52 or 17.8% decrease by 2012 for a total average cost of $520.81. By CY2013 the total average cost is projected at $461.43 which reflects a $59.38 or 11.4% decrease in the cost. However, the applicant failed to budget for necessary administrative staff. See Criterion (7) for discussion. Therefore, expenses and average cost per procedure are understated.

In summary, OMLLC failed to document the availability of sufficient funds for the capital and working needs of the project. OMLLC also failed to demonstrate that the financial feasibility of the project is based on reasonable projects of costs and revenues. See Criterion (3) for discussion. Therefore, the application is not conforming to this criterion.

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

NC
Both Applicants

CDI proposes to acquire no more than one fixed MRI scanner to operate at its existing facility in Onslow County. The 2009 SMFP determined a need for one fixed MRI scanner in the Onslow MRI service area. However, the applicant does not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI services. See Criterion (3) for discussion. Therefore, the applicant did not adequately demonstrate that the proposed project would not result in

Attachment 3

From: <ajames@vfdental.com>
Subject: Valleygate Dental Surgery Centers
Date: May 10, 2016 at 11:39:55 AM EDT
To: <vjones@vfdental.com>
Cc: <wholding@pda-inc.net>

Dear Colleagues,

By now, you may have received emails regarding dental ambulatory surgery centers, some of which have asked you to "DocuSign" letters of support and/or show intent to bring patients to a proposed surgery center. Please be aware, multiple options exist.

Valleygate Dental Surgery Centers also proposes to establish dental surgery centers, but with a different scope from others seeking to do so. As a 31-year-old practice with over 40 dentists including 8 pediatric dentists and 3 oral surgeons, Valleygate's organizer, Knowles, Smith, McGibbon, Ryan, James, Patel & Associates LLP believes that the majority of demand for dental surgery under general anesthesia is in the pediatric and special needs population. However, we also recognize the need for an alternative to hospitals or multi-specialty ambulatory surgery centers (ASCs) for certain adult dental and oral surgery procedures. As a result, Valleygate is collaborating with the Carolinas Center for Oral and Facial Surgery to design the facility program and scope. The centers will provide for patients who meet the clinical qualifications for hospitals or ASCs. Our model will provide full time Anesthesiologists and CRNA staffing. A CMS-recognized accrediting body such as, AAAHC will certify facilities.

The most important thing for you to understand is that multiple options exist. We agree that the state of North Carolina is offering an important solution to operating room access problems. Because it's a one-time demonstration project, we think it should be done properly reflecting the needs of dental professionals, while preserving the integrity and respect of our profession in the public eye. **The NC Dental Society has endorsed only our proposal, and the responsibility this caries is one we take very seriously**. In the various areas of the state, only one facility will be approved, despite multiple applicants. Communication from other organizations seeking to establish surgery centers suggests that state CON approval hinges on letters of support from the dental community. In fact, state's decision to award a certificate of need to one applicant over another will hinge upon the viability of the project, the ability to serve true and measurable clinical need, and the ability to build a cost-effective and safe solution. Our stance is that we must build a facility that measurably improves access problems and will be administered by highly qualified clinicians specifically trained to treat patients under sedation and general anesthesia. Our proposal ensures that dentists remain good stewards of our fiscal responsibilities to the taxpayer as well as our ethical oaths to patient care and safety.

Valleygate seeks to form collaborative partnerships in the various regions of the state with no intent to control the entire state with these proposals. If you are interested in more information, please respond to this email and we will contact you personally. Just as all dental offices in this state are owned by dentists, Valleygate ASCs will be owned and managed by only North Carolina dentists. We are seeking to establish centers in Fayetteville, Raleigh, Charlotte, and the Triad area.

If the concept is of interest to you, but you prefer to remain neutral, please reply to this email and indicate your support for the concept and the number of patients you may bring or refer monthly.

Respectfully yours,

Anuj James, DDS

Valleygate Dental Surgery Centers

For your convenience, feel free to reply using the following format:

I support having a dental only surgical center in _____ (Charlotte, Triad, Fayetteville, or Raleigh)

I would refer _____ patients a month

I would do _____ procedures a month in the facility, if credentialed.

KSA: Michael Knowles, DMD • Terrance Smith, DDS • Faith McGibbon, DDS • Brad Ryan, DDS •
Mit Patel, DDS • Grant Wiles, DDS • Anne Dodds, DDS

CCOFS: Brian B Farrell DDS, MD • Bart C Farrell DDS, MD • John C Nale DMD, MD • Daniel C Cook DDS MD •
Richard A Kapitan DDS, MS • Waheed V Mohamed DDS, MD • Dale J Misiek DMD

Attachment 4

From: Valleygate Surgical Centers <valleygatesurgerycenter@gmail.com>
Date: May 13, 2016 at 5:35:25 PM EDT
To:
Subject: NC Dental Society
Reply-To: valleygatesurgerycenter@gmail.com

Dear Colleagues,

Recently, you received an email from me regarding our proposed Valleygate dental surgery centers. We are writing to clarify a misstatement in that e-mail. While the North Carolina Dental Society supports the concept of a demonstration project for a single specialty dental ambulatory surgery center, they have not endorsed Valleygate's proposal. We apologize for the inaccuracy of our previous email.

We have been in communication with the North Carolina Dental Society leadership and want to be clear. As far as we are aware, the North Carolina Dental Society does not support any one dental surgery center project over another.

Please accept our apologies for the mistake. Thank you for your understanding. Our intent is to find a solution for underserved children.

Yours,

Anuj James, DDS

Valleygate Dental Surgery Centers

Dental Society Letter 5-12-16

Dental Society Letter 7-27-15

Attachment 5

NORTH CAROLINA DENTAL SOCIETY | ADA

May 16, 2016

Dear Colleagues:

In the 2016 State Medical Facilities Plan for North Carolina, the NC Division of Health Services Regulation (DHSR) determined that there is a need for a demonstration project for ambulatory surgical facilities devoted solely to dentistry. As a result, the DHSR is in the process of accepting and reviewing certificate of need (CON) applications for a total of four (4) such facilities in various parts of the state.

As the 2016 State Plan was being developed last summer, the NCDS submitted a letter to the DHSR dated July 27, 2015. That letter expressed our support "for a demonstration project of a single specialty dental ambulatory surgical center to serve the needs of children covered by Medicaid who are experiencing significant barriers to dental care." The letter further pointed out that many of these children experience "complex dental problems" requiring treatment under general anesthesia and can face extended wait times because of limited access to operating room facilities.

We have just learned that one of the CON applicants, Valleygate Dental Surgery Centers, inaccurately claimed in emails variously dated May 10 and May 11 that the NCDS has endorsed its CON application. This is simply not the case, and we have asked Valleygate Dental Surgery Centers to stop making such a claim and issue a retraction to all of the recipients of its e-mails.

While the NCDS continues to support the dental ambulatory surgical center demonstration project, we have been careful at this time not to endorse any specific CON applicant. Based on the information we have to date, we believe it should be up to the DHSR to determine which, if any, applicant meets its very specific criteria for access, value and safety as published in the 2016 State Plan. Individual members of the NCDS are free to decide for themselves whether to support any specific CON application. It must be noted, however, that such support by an individual NCDS member does not represent an endorsement by the NCDS.

Thank you for your understanding as we work to resolve this issue.

Sincerely,

Ronald Venezie

Ronald Venezie, DDS, President
North Carolina Dental Society

Attachment 6

----- Forwarded Message -----
From: Virginia Jones <VJones@vfdental.com>
To: [redacted]
Sent: Monday, May 9, 2016 8:00 AM
Subject: Letters of support and information

[redacted],

Thank you so much for your time on Thursday. I am finally back in the office to send you a copy of the letter we have requested, and if you would share it with your colleagues. We would need them back by May 24th, and they can just be emailed to me, we will gather, then send to the state. As we discussed, all applications can be supported.

A few points to summarize what we talked about from an investment perspective.

Ownership in ASC practice – Knowles, Smith & Associates (VFD) would like to retain 15% of the ownership in the ASC practice. We think a total of 6-8 practice owners is appropriate, which each practice, regardless of the percentage, having one vote on the Board. We believe that ownership should be made up of local dentists in the area where the ASC is located, preferably pediatric dentists and oral surgeons. VFD can provide management services if desired at 3.5% for the first three years. However, the practices in the area know what is best for their operations, so we want to protect that interest. In addition, the facility is dental owned only to honor the NC dental practice act.

Real estate – the real estate is currently negotiated as a "build to suit" lease. However, the owners of both options are willing to sell the land. The location has been determine thru an in-depth analysis of the need and geographical accessibility of these patients, according to CON guidelines. If the pediatric dentists in the area, either one, two or all, would prefer to own the real estate, then VFD can help introduce all parties, and those dentists can purchase the land and build the facility. The drawings have already been designed, prepared, and reviewed. Therefore, construction costs will be less. VFD is not interested in real estate ownership.

VFD has always believed that these facilities should be for dentists, by dentists, and meet a real and measurable problem that exists, primarily in the pediatric dental community. By creating a collaboration amongst your peers, this will insure that this mission will be accomplished.

I have attached the financial projections included in our application. Note that these are EXTREMELY conservative, assuming 95 percent Medicaid, 5% charity, and a very low reimbursement rate. If the center can make it with these numbers, then the true numbers we have and believe we can accomplish are easily met. Our CPA Firm, Elliott Davis, is working on a formal prospectus to share. However, as discussed, we are not looking for a large number of small investors. We are looking for 6-8 dental partners.

Thanks again for your time. It was a pleasure to meet you!

Ginny

Virginia Jones
Chief Operating Officer
Village Family Dental
(910) 485-7070 ext 2612
Check us out on the web: http://www.vfdental.com/
Or on Facebook: https://www.facebook.com/vfdental/

Attachment 7

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	September 27, 2011
FINDINGS DATE:	October 4, 2011
PROJECT ANALYST:	Michael J. McKillip
SECTION CHIEF:	Craig R. Smith
PROJECT I.D. NUMBER:	**J-8660-11**/WakeMed/Add 79 acute care beds on the WakeMed Raleigh Campus/Wake County
	J-8661-11/WakeMed/Add 22 acute care beds at WakeMed Cary Hospital/Wake County
	J-8667-11/Rex Hospital, Inc./Add 11 acute care beds and construct a new beds tower to replace 115 acute care beds in a change of scope for Project I.D. # J-8532-10 (heart and vascular renovation and expansion project)/Wake County
	J-8669-11/Rex Hospital, Inc./Develop a new separately licensed 50-bed hospital in Holly Springs/Wake County
	J-8670-11/Rex Hospital, Inc./Develop a new separately licensed 40-bed hospital in Wakefield/Wake County
	J-8673-11/Holly Springs Hospital II, LLC/Develop a new 50-bed hospital in Holly Springs/Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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

the three applications proposing to develop new acute care hospitals, since the applications propose to develop new acute care hospitals that are similar in size and scope of services.

Operating Costs Comparison - Third Year of Operation

Applicant	Operating Costs	Adjusted Patient Days	Operating Costs Per Adjusted Patient Day
Existing Hospitals			
WakeMed Raleigh	$690,406,305	288,003	$2,397
WakeMed Cary	$172,851,617	92,459	$1,870
Rex Hospital*	$151,207,160	51,383	$2,943
New Hospitals			
Rex Holly Springs	$68,155,407	27,202	$2,506
Rex Wakefield	$52,383,001	20,544	$2,550
Novant Holly Springs	$57,903,869	23,500	$2,464

*Rex Hospital does not provide operating costs and adjusted patient days for the entire hospital, but only for the 11 new acute care beds, 115 existing acute care beds to relocated to the proposed bed tower, and other related services identified in the application.

As shown in the table above, WakeMed Cary projects the lowest operating cost per adjusted patient day in the third year of operation, and Rex Hospital projects the highest operating costs per adjusted patient day in the third year of operation. However, the projections for Rex Hospital do not include the entire hospital, but only the program components involved in the proposed project. The remaining applicants project comparable operating costs per adjusted patient day. However, operating cost per adjusted patient day projected by Novant Holly Springs are not reliable to the extent they are based on projected utilization. Novant Holly Springs did not adequately demonstrate that its projected utilization is based on reasonable and supported assumptions. See Criterion (3) for additional discussion. Thus, any comparison of average operating cost per adjusted patient day for Novant Holly Springs to the other applications is questionable.

Documentation of Physician Support

Documentation of support from Wake County physicians for a proposed project to add new acute care beds is considered an important factor in this review. In Exhibit 49, WakeMed Raleigh provided letters from 255 physicians in Wake County and surrounding communities expressing their support for the proposed project. In Exhibit 49, WakeMed Cary provided letters from 244 physicians in Wake County and surrounding communities expressing their support for the proposed project. In Exhibit 54, Rex Hospital provided letters from 296 physicians in Wake County and surrounding communities expressing their support for the proposed project. In Exhibit 66, Rex Holly Springs provided letters from 319 physicians in Wake County and surrounding communities expressing their support for the proposed project. In Exhibit 62, Rex Wakefield provided letters from 318 physicians in Wake County and surrounding communities expressing their support for the proposed project. In

Exhibit 14 of the application, Novant Holly Springs provided letters from 95 physicians in Wake County and surrounding communities expressing their support for the proposed project. However, the Novant Holly Springs' application did not contain any letters of support from Wake County obstetricians. See Criteria (3) and (8) for discussion. Therefore, with regard to documentation of physician support from Wake County and surrounding communities, WakeMed Raleigh, WakeMed Cary, Rex Hospital, Rex Holly Springs, and Rex Wakefield are determined to be comparable, and Novant Holly Springs is determined to be the least effective alternative.

SUMMARY

The following is a summary of the reasons **Rex Holly Springs** is determined to be an effective alternative in this review:

- Adequately demonstrates the need the population projected to be served has for the proposed acute care beds. See Criterion (3) for discussion.
- Adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Proposes to expand geographic access to acute care bed services for the residents of southern Wake County by developing a new hospital in Holly Springs.
- Projects the highest percentage of total services to be provided to Medicare recipients of the three applicants proposing to develop a new hospital.
- Projects the second lowest gross revenue per adjusted patient day of all the applicants in the third year of operation.
- Projects the lowest net revenue per adjusted patient day in the third year of operation of the three applicants proposing to develop a new hospital.
- Projects operating costs per adjusted patient day in the third year of operation that are comparable with the other applicants proposing to develop new hospitals.
- Provides documentation of a relatively high level of physician support from physicians in Wake County and surrounding communities.

The following is a summary of the reasons **WakeMed Cary** is determined to be an effective alternative in this review:

- Adequately demonstrates the need the population projected to be served has for the proposed acute care beds. See Criterion (3) for discussion.
- Adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Projects the second highest percentage of total services to be provided to Medicaid recipients of the three applicants proposing to add acute care beds to an existing hospital.
- Of the applicants proposing to develop additional acute care beds at an existing hospital, WakeMed Cary has the highest projected deficit of acute

care beds in 2014, based on the Proposed 2012 SMFP, Table 5A: Acute Care Bed Need Projections.
- Projects the lowest net revenue per adjusted patient day in the third year of operation of all the applicants.
- Projects the lowest operating cost per adjusted patient day in the third year of operation of all the applicants.
- Provides documentation of a relatively high level of physician support from physicians in Wake County and surrounding communities.

The following is a summary of the reasons **WakeMed Raleigh**, as conditioned, is determined to be an effective alternative in this review:
- Adequately demonstrates the need the population projected to be served has for the proposed acute care beds. See Criterion (3) for discussion.
- Adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Projects the highest percentage of total services to be provided to Medicaid recipients of all the applicants.
- Of the applicants proposing to develop additional acute care beds at an existing hospital, WakeMed Raleigh has the second highest projected deficit of acute care beds in 2014, based on the Proposed 2012 SMFP, Table 5A: Acute Care Bed Need Projections.
- Projects the second lowest net revenue per adjusted patient day in the third year of operation of all the applicants.
- Projects the second lowest operating cost per adjusted patient day in the third year of operation of all the applicants.
- Provides documentation of a relatively high level of physician support from physicians in Wake County and surrounding communities.

The following is a summary of the reasons each of the other applicants is found to be a less effective alternative for the development of additional acute care beds than **Rex Holly Springs, WakeMed Cary**, and **WakeMed Raleigh**.

Rex Hospital
- Projects the second lowest percentage of total services to be provided to Medicaid recipients of all the applicants.
- Of the three applications proposing to develop additional acute care beds at an existing hospital, Rex Hospital is the only applicant with a projected surplus of acute care beds in 2014, based on the Proposed 2012 SMFP, Table 5A: Acute Care Bed Need Projections.
- Projects the second highest gross revenue per adjusted patient day in the third year of operation of all the applicants.
- Projects the highest net revenue per adjusted patient day in the third year of operation of all the applicants.
- Projects the highest operating cost per adjusted patient day in the third year of operation of all the applicants.

- Proposes a location for the acute care beds that is less effective with regard to improving geographic accessibility.

Rex Wakefield

- Projects the lowest percentage of total services to be provided to Medicaid recipients of all the applicants.
- Projects the highest gross revenue per adjusted patient day in the third year of operation of the three applicants proposing to develop new acute care hospitals.
- Proposes a location for the acute care beds that is less effective with regard to improving geographic accessibility.

Novant Holly Springs

- Does not adequately demonstrate the need the population projected to be served has for the proposed acute care beds. See Criterion (3) and 10A NCAC 14C .3803 for discussion.
- Does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable and supported projections of revenues and operating costs. See Criterion (5) for discussion.
- Does not adequately demonstrate that the proposed services will be coordinated with the existing health care system. See Criterion (8) for discussion.
- Projects the highest net revenue per adjusted patient day in the third year of operation of the three applicants proposing to develop new acute care hospitals, and the second highest net revenue per adjusted patient day in the third year of operation of all the applicants.
- Projects the lowest percentage of total services to be provided to Medicare recipients of all the applicants.
- Provides documentation of a relatively low level of physician support from physicians in Wake County and surrounding communities.

CONCLUSION

NC General Statute 131E 183 (a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the CON Section. The CON Section determined that the applications submitted by Rex Holly Springs, WakeMed Cary, and WakeMed Raleigh are the most effective alternatives proposed in this review for 101 acute care beds in Wake County and are approved, as conditioned below. Also, the application submitted by Rex Hospital is approved as conditioned below. The approval of any other application would result in the approval of acute care beds in excess of the need determination in the SMFP and therefore, the Rex Wakefield and Novant Holly Springs applications are denied.

The application submitted by Rex Holly Springs is approved subject to the following conditions.