Comments on Valleygate Dental Surgery Center of Raleigh

submitted by

Surgical Center for Dental Professionals of Raleigh

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Surgical Center for Dental Professionals of Raleigh (SCDP of Raleigh) submits the following comments related to Valleygate Dental Surgery Center of Raleigh's (VDSCR) application to develop a new dental surgery center. SCDP of Raleigh'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 Raleigh 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 VDSCR, Project ID # J-11175-16.

GENERAL COMMENTS

While the comments below will discuss the multiple specific deficiencies in the VDSCR application that necessitate its denial, SCDP of Raleigh believes that an overall comparison of the applications demonstrates the clear superiority of its proposed project over that of VDSCR. The VDSCR 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 VDSCR'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 19)
- *"Valleygate Dental Surgery Center of Raleigh's primary focus will be pediatric dental surgery performed by pediatric dentists"* (page 20)

In its application, VDSCR ignores the need by adult patients to access licensed surgical facilities and limits their proposed service to mostly pediatric patients. In contrast, SCDP of Raleigh 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 Raleigh'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 reduce the number of general dentists who are allowed to perform sedation cases in their offices;
- VDSCR'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, VDSCR 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 41). This is a clear disagreement with the requirement for a wide range of access by the dental ambulatory surgery center demonstration projects. SCDP of Raleigh 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 Raleigh'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. (pages 20-21). 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 Valleygate Dental Surgery Center of Fayetteville (VDSCF) application, a concurrently filed CON. 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, VDSCR's assertion that only a small fraction of adults require care in a licensed facility is not supported. First, as noted below, VDSCR's assumed largest referral source, WakeMed, provides 22 percent of its dental surgery cases to adults. 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, VDSCR'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.

VDSCR 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 Raleigh*" (page 19).

While this requirement may be clinically necessary since VDSCR does not require anesthesiologist coverage for all its cases, as SCDP of Raleigh 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 to perform these cases and would be eligible to be credentialed at SCDP of Raleigh based on their expertise and not based on sedation certification. SCDP of Raleigh 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 VDSCR'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, VDSCR'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 Raleigh 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, VDSCR'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. VDSCR'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, VDSCR's application does not meet the requirements of the demonstration and should be found non-conforming with Criterion 1. As such, VDSCR should be denied.

APPLICATION-SPECIFIC COMMENTS

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

(1) Insufficient information regarding the site and financing for the project;
(2) Unsupported methodology and assumptions for utilization;
(3) Unsupported methodology and assumptions for age and payor mix;
(4) Unreasonable financial projections; and,
(5) Failure to demonstrate reasonable design.

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

INSUFFICIENT INFORMATION REGARDING THE SITE AND FINANCING FOR THE PROJECT

The application provides conflicting and contradictory information regarding both the financing for, and the proposed site of, the project.

The named applicant in this review is Valleygate Dental Surgery Center of Raleigh, LLC (VDSCR). According to Section VIII of the application, the total capital cost of the project is $3,750,187. According to Section IX, the total working capital required is $664,073. Therefore, VDSCR must demonstrate the availability of $4,414,260 for capital and operating needs, in order to be conforming with Criterion 5.

The VDSCR application proposes to finance both capital and operating needs through a conventional loan with First Citizens Bank. In this regard, VDSCR references a letter from First Citizens in Exhibit 38 to the application. That letter appears to indicate that First Citizens is willing to loan the necessary funds to VDSCR. However, the letter also indicates that part of the basis for that loan is First Citizens' understanding that the VFD Real Estate Partners, LLC (VFD), with which First Citizens has an ongoing relationship, would be the developer of the building in which the surgery center would be located. According to Sections I and XI of the application, VFD is not an applicant and does not own either site proposed in the application. Therefore, it does not appear that one of the conditions upon which the First Citizens would agree to loan the funds exists.

Further complicating the issue is the fact that Sections I and XI of the application state that VDSCR will lease the site from G K Murthy and Bhanratha L. Manne, the true owners of the primary site ("lessors"), but the letter of intent attached as Exhibit 1 to the application signed by the lessors is with VFD, not VDSCR. VDSCR, is not identified in this document. There is no provision in the letter of intent for either party to assign its interest in the lease or for VFD to sublease the facility, nor is there anything in the CON application indicating that VFD is willing to do so. There also is no proposed sublease in the application.

The materials contained in Exhibit 47 of the application regarding the proposed secondary site have the same problems - the letter of intent setting forth the proposed lease terms is between the property owners and VFD, not the applicant. As with the primary site, there is no indication of the ability of or intent by VFD to assign its interest in the lease or sublease the property to VDSCR.

The NC Court of Appeals addressed a similar issue in *Retirement Villages, Inc. v. NC DHHS*, 124 N.C.App. 495, 477 S.E.2d 697 (1996). There, the applicants, Beaver Properties/Wallace, Inc. and Brian Center Health & Retirement/Wallace, Inc. (collectively "Beaver Properties") filed a CON application to add beds to their existing nursing facility in Duplin County. The applicants' projected capital costs of $227,380, which they stated would be paid with a conventional loan of $204,642 and owner's

equity of $22,738. However there was no information in the application showing that the applicants had access to funds for the project. There was financial information about two related entities, Brian Center Management Corporation ("BCMC") and Brian Center Corporation ("BCC"), including a letter from NationsBank indicating its interest in loaning BCMC $204,642 for the addition/conversion and confirming that BCC had in excess of $22,738 which could be used to fund the project. However, there was nothing in the application indicating that NationsBank was willing to loan funds to Beaver Properties, or that BCC or BCMC was willing to make those funds available for the project. The Court of Appeals found that based on this information, Beaver Properties had not demonstrated the availability of funds for the project, and was non-conforming with Criterion 5.

Similarly, because (1) First Citizens' letter indicating a willingness to loan funds to VDSCR is contingent on VFD's involvement as the developer of the building, which is not going to occur; and (2) because the letters of intent attached to the application do not show a willingness by the proposed landlord to enter into a lease with VDSCR, or the ability or willingness of VFD to assign its right under the letter of intent or to sublease the space to VDSCR, it appears that the applicant has failed to demonstrate that it has access either to the funds necessary to develop the project or to a site on which it can develop the project. **Without either, VDSCR cannot demonstrate conformity with Criteria 4, 5, and 12, and should be denied.**

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR UTILIZATION

On page 116 of its application, VDSCR provides a list of estimated cases by referral source as excerpted below:

Table IV. 2 – Estimated Cases for VDSCR Referral Sources, as of April 15, 2016

Source	Cases
WakeMed	933
Antonio Braithwaite	500
Jordan Olsen	120
Dr. Wang	24
Ann Dodds	432
Dr. Fisher	60
Dr. Corliss Furber	72
Dr. Jenny Tu	48
Granville Vance Health Dept	12
Advance FQHC	120
Amy Davidian	36
David Ravel, DDS	72
Total	**2429**

Note: These are low estimates. WakeMed cases estimated from files provided.

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 below, these referral estimates are unsupported and unreasonable.

WakeMed

VDSCR states that WakeMed will be referral source for 933 cases. On page 117 of its application, VDSCR states: "[i]*n its letter, WakeMed indicates clear its support for transitioning providers and dental cases to an approved, dental only ambulatory surgical facility. According to data obtained from WakeMed, providers completed 1,122 dental surgery cases in 2015, 1,037 were outpatient. Most of the outpatient cases would be candidates for surgery in the proposed dental ASC. Assume the pattern is consistent* [sic] *and 90 percent of the cases that went to WakeMed used the new dental ASC. Then the WakeMed referral base would be (1,037 times 90% = 933) cases.*

VDSCR's assumptions for these WakeMed cases are unreasonable. First, WakeMed is clear in its letter that dentists perform these cases, not WakeMed itself, and that WakeMed would support those dentists if they wished to move their cases. Specifically, WakeMed's letter states that *"WakeMed will support the transition of appropriate dental surgery procedures from WakeMed's surgical department to Valleygate Dental Surgery Center of Raleigh. WakeMed will support dentists who wish to transition cases away from WakeMed to the proposed center"* (Exhibit 15 of VDSCR). Thus, the referral source for these cases is the individual dentists that perform them, not WakeMed. VDSCR does not provide any

information or support from the dentists that perform these cases. As such, there is no basis for the assumption that these dentists practicing at WakeMed can or would shift cases to VDSCR. VDSCR does not provide any information that these dentists wish to move their cases to VDSCR, beyond WakeMed's letter which indicates that it would support the dentists that wished to move their cases.

VDSCR's application does not include the WakeMed data that is the basis for this assumption. However, SCDP of Raleigh was given the same data set by WakeMed. The WakeMed data set does not include the names of the dentists that performed these cases; the dentist name variable is anonymized. It is possible that cases performed by VDSCR's supporting dentists are already included in the WakeMed data and are thus double-counted. VDSCR's application does not provide any information to indicate whether these cases are double-counted. There is no information provided about the location where its other supporting dentists have historically practiced and no information about which dentists are included in the WakeMed data.

Of note, several dental professionals that have expressed written interest in investing and performing cases at SCDP of Raleigh have historically performed cases at WakeMed including among others, Dr. David Kornstein, the proposed medical director for SCDP of Raleigh. These dental professionals have expressed their clear support for SCDP of Raleigh, not VDSCR. As noted throughout these comments, VDSCR's proposal is restrictive for patient and physician access when compared to SCDP of Raleigh. Many dental professionals, including those who have historically performed cases at WakeMed, have expressed their support for SCDP of Raleigh's proposal and not for VDSCR. Thus, VDSCR's assumption that providers would move their cases to VDSCR from WakeMed is unreasonable, as these physicians do not support VDSCR. Given this available evidence, it is clear that VDSCR's assumption that these cases will shift from WakeMed is unsupported and unreasonable.

Finally, VDSCR provides no basis for its assumption that 90 percent of WakeMed outpatient cases would be referred to VDSCR. VDSCR states "[a]*ssume the pattern is consistent* [sic] *and 90 percent of the cases that went to WakeMed used the new dental ASC*" (page 117). It is unclear to what pattern VDSCR is referring. VDSCR provides no basis for determining that 90 percent of WakeMed's outpatient cases would be appropriate for VDSCR. WakeMed states in its letter that "[s]*ome of the cases will still be too complex even for this new program*" (Exhibit 15), but there is no information provided to determine that the 90 percent assumption is reasonable. In summary, VDSCR's assumptions for the inclusion of WakeMed referrals in its projected utilization are unsupported.

Antonio Braithwaite

VDSCR states that Antonio Braithwaite will be the source for 500 cases annually. This is unsupported by two letters of support from Dr. Braithwaite's practice. As shown in

Exhibit 26 of VDSCR's application, the two letters of support from Dr. Braithwaite's practice do not indicate that this group plans to perform these cases at VDSCR. The letters note that last year Dr. Braithwaite's practice *"had three days per week in the operating room and [was] able to treat nearly 500 patients."* The letters do not indicate whether any of those nearly 500 cases would be shifted to VDSCR. Nonetheless, VDSCR has assumed that Dr. Braithwaite's practice will perform 500 cases at VDSCR, which is more than provided historically as the letters specifically note that last year the volume was nearly 500. For these reasons, VDSCR's projections for Dr. Braithwaite's cases are unsupported.

Dr. Wang

VDSCR states that Dr. Wang will be the source of 24 cases annually. Dr. Zhengyan Wang's letter of support in Exhibit 26 states *"I will refer patients to the dentists who use the facility, approximately 1-2 per month."* VDSCR states on page 116 of the application, underneath the table excerpted above, *"Note: These are low estimates."* It appears that VDSCR made a typographical error and listed 24 cases based on Dr. Wang's high estimate rather than 12 cases based on the low estimate, which would be consistent with its note and with the low estimates used for each other dentist who provided a letter of support with referral numbers. For this reason, VDSCR's projections for Dr. Wang's cases should be corrected to 12 cases annually.

Ann Dodds

VDSCR states that Dr. Ann Dodds, *"the proposed Clinical Director of the facility will bring many pediatric patients to the facility. Dr. Dodds currently practices in Fayetteville with Knowles, Smith and Associates, but resides in Durham"* (page 117). In her letter, Dr. Dodds states *"I am writing this letter ... to express my desire to use the facility for the treatment of my own dental patients . . . I plan to work three days per week seeing 3-4 patients per clinical day"* (Exhibit 26). It is not clear from Dr. Dodds' letter or from the representations made in the application whether the proposed patients attributable to Dr. Dodds are based on her existing patient panel which is based in Fayetteville or would be new patients from Garner. These are likely to be new patients given her current location and there is no way of knowing whether Dr. Dodds' estimate of 432 patients annually is reasonable as she would be a new practitioner in the service area. Further, no other single KSA dental professional that projects to practice at the VDSCR or VDSCF has projected as many as 432 cases annually or 36 cases per month. Thus Dr. Dodds is projected to be the busiest dental professional in her practice in a new market. While some of these patients might be referrals from other dental professionals, VDSCR has not indicated who would provide those referrals as all of its non-user referrals (such as the 1-2 per month from Dr. Wang) are counted separately. For these reasons, VDSCR's projections for Dr. Dodds' cases are unsupported.

Dr. Fisher

VDSCR states that Dr. Fisher will be the source of 60 cases annually. On page 13 of VDSCR's application, Dr. Elda Fisher is listed as a member of the Southeastern Dental Specialists practice of Village Family Dental/Knowles, Smith, and Associates and VDSCR specifically lists Dr. Fisher as a dental professional who does not plan to practice at the facility, as shown in the first sentence below excerpted from page 13 of VDSCR's application.

General and Specialized Dentists and Oral Surgeons

Although they do not plan to practice in the facility, other professionals will be available to consult with the applicant. Village Family Dental includes all other dental specialties, including general dentists, endodontists, periodontists, orthodontists, and oral surgeons. Three Oral and Maxillofacial surgeons are members of the Southeastern Dental Specialists practice of Village Family Dental:

- Anthony Maiorana, a Diplomat of the National Dental Board of Anesthesiology, Fellow of the American Dental Society of Anesthesiology and a member of the American Association of Oral and Maxillofacial Surgeons;
- Elda Fisher, MS, DMD, MD, who received her degrees from the New Jersey Dental School and UNC School of Medicine. She is fluent in Spanish as well as English; and,

Dr. Fisher's letter of support is included in Exhibit 33-Letters of Support-Other Healthcare Support, not Exhibit 26 where the other letters from referral sources and users are located. In fact, Dr. Fisher does not provide an estimate of the number of cases that she will refer or perform at the facility. As such, there is no support for the 60 cases annually assumed by VDSCR. Even assuming that Dr. Fisher does perform cases at VDSCR, like Dr. Dodds, it is not clear from the letter or from the representations made in the application whether the proposed patients attributable to Dr. Fisher are based on her existing patient panel which is based in Fayetteville or would be new patients from Garner. If these patients are drawn from Dr. Fisher's existing panel, it is not clear why 60 Fayetteville area patients would travel to Garner for their care. If those patients are new patients, then there is no way of knowing whether the estimate of 60 patients annually for Dr. Fisher is reasonable as she would be a new practitioner in the service area. For these reasons, VDSCR's projections for Dr. Fisher's cases are unsupported.

Granville Vance Health Dept

VDSCR states that the Granville Vance Health Department will be the source of 12 cases annually. A letter from the Granville Vance Health Department is included in Exhibit 33

but provides no estimate of the number of cases that would be referred to VDSCR. For these reasons, VDSCR's projections for the Granville Vance Health Department cases are unsupported.

Advance FQHC

VDSCR states that Advance FQHC will be the source of 120 cases annually. A letter from Advance Community Health is included in Exhibit 33 but provides no estimate of the number of cases that would be referred to VDSCR. For these reasons, VDSCR's projections for the Advance FQHC cases are unsupported. Of note, Advance Community Health provided a letter of support for SCDP of Raleigh's application on page 681 without providing any specific number of cases to be referred. For that reason, SCDP of Raleigh did not include any projected referrals from Advance Community Health.

David Ravel, DDS

VDSCR states that Dr. Ravel will be the source of 72 cases annually which corresponds to his letter of support in Exhibit 26. However, on page 14 of its application, VDSCR lists Dr. Ravel and other KSA pediatric dentists and notes that with the exception of Jordan Olsen and Ann Dodds, the other KSA pediatric dentists, including Dr. Ravel, plan to utilize VDSCF, as shown in the excerpt below.

> KSA's current Pediatric Dentists are:
>
> - Faith McGibbon, DDS
> - Jordan Olsen, DDS
> - Trina Collins, DDS
> - Richard Burke, DMD
> - Daniel Ravel, DDS
> - Alan Babigan, DDS
> - Anne Dodds, DDS
> - Martin Oakes, DDS
>
> With the exception of Jordan Olsen, who practices in both the Fayetteville and the Raleigh area, and Anne Dodds, who resides in Durham and will be serving as the Clinical Director for the proposed facility, the other KSA pediatric dentists plan to access another dental ambulatory surgery center proposed for Fayetteville.

Like Dr. Dodds and Fisher, it is unclear whether the proposed patients attributable to Dr. Ravel are based on his existing patient panel which is based in Fayetteville or would be new patients from Garner. Further, Dr. Ravel is listed as a user on page 36 of VDSCF. There is no information provided to determine where Dr. Ravel will practice if one or more of the facilities is approved. For these reasons, VDSCR's projections for Dr. Ravel's cases are unsupported.

Summary

As discussed above, VDSCR utilization assumptions are unsupported by the evidence provided for a number of the specified referral sources. The table below provides a comparison between estimated cases from the VDSCR's application and those for which VDSCR has supported assumptions:

Table IV.2-Estimated Cases for VDSCR Referral Sources, as of April 15, 2016

Source	*Cases*	*Documented by Letters of Support Committing to Perform Cases*
WakeMed	933	0
Antonio Braithwaite	500	0
Jordan Olsen	120	120
Dr. Wang	24	12
Ann Dodds	432	0
Dr. Fisher	60	0
Dr. Corliss Furber	72	72
Dr. Jenny Tu	48	48
Granville Vance Health Department	12	0
Advance FQHC	120	0
Amy Davidian	36	36
David Ravel, DDS	72	0
Total	**2,429**	**288**

As shown above, VDSCR's application only shows 288 cases with documented support. This level of utilization is well below its projected 2,500 to 3,000 cases annually and well below the number of cases required to demonstrate the need for the two proposed operating rooms according to the demonstration project standard of 900 cases per room.

VDSCR has not demonstrated the need for the proposed project and its application should be found non-conforming with Criteria 1, 3, 4, 5, and 12. As such, VDSCR should be denied.

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR AGE AND PAYOR MIX

VDSCR's projections for the percent of patients by age group and by payor class are unsupported and unreasonable. As VDSCR states on page 159 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.6 by the estimated percent of persons over 21 (adults) in year two from Table IV.7 (8.82 percent).*" As shown in Table IV.7 on page 121, 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. VDSCR 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, VDSCR provides no information to indicate that its age mix will be identical to that of the Medicaid population statewide. Second, VDSCR provides no information to indicate that the age mix of patients in the Wake County area are identical to the Medicaid population statewide. Finally, VDSCR makes no attempt to account for the age mix for its specific referral sources. For example, according to data provided by WakeMed to VDSCR (and SCDP of Raleigh), 21.9 percent of the WakeMed patients that VDSCR assumes will shift to its facility are over 21 years of age. Thus, WakeMed has an adult patient population far in excess of what is assumed by VDSCR. VDSCR notes on page 116 of its application that WakeMed referrals constitute the largest single source of referrals, 38 percent of the total (38 percent = 933 WakeMed referrals ÷ 2,429 total referrals). VDSCR did not adjust its projected age mix to account for the WakeMed-specific age mix and thus its assumptions are unreasonable.

Similarly, VDSCR's projections for payor mix by age group are based on the historical payor mix for KSA and make no attempt to adjust for WakeMed's payor mix, its largest source of referrals. This is also unreasonable for several reasons. First, as noted above, VDSCR's projections for patients by age group are unsupported. Second, KSA is an existing dental practice with several offices, none of which are in VDSCR's proposed service area. Thus, there is no relationship between the projected patient population of VDSCR and the historical patient population of KSA. VDSCR provides no information to support the assumption that VDSCR's payor mix will be identical to KSA's historical payor mix, especially given the geographic differences in the populations.

Additionally, VDSCR does not provide estimated payor mix for charity care and self-pay patients separately as specified in Criterion 10-Demonstration Project. This is important, not only because it is specified in the Demonstration Project criteria, 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, VDSCR has overstated its charity care contribution.

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

VDSCR 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

and 13(c). Nor can its age mix or payor mix be used to show comparative superiority or conformity with the dental single specialty ambulatory surgical facility demonstration project. As such, VDSCR should be denied.

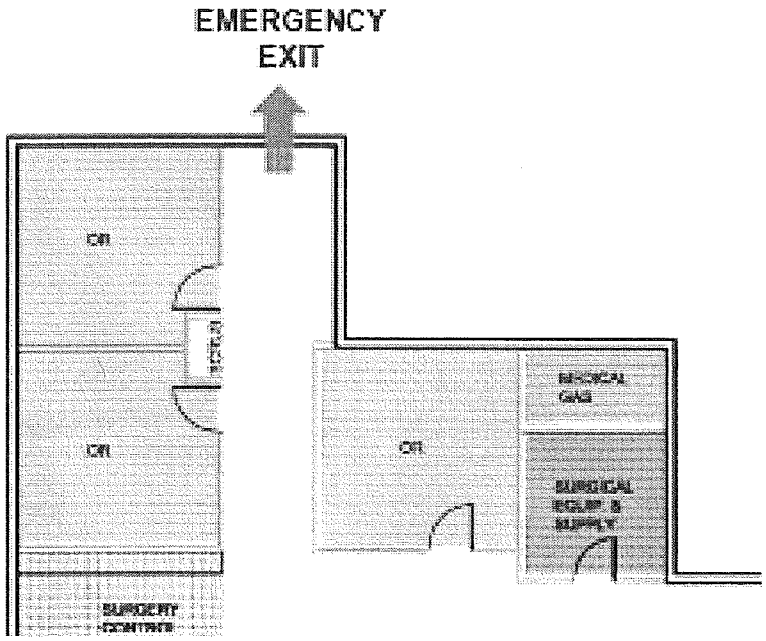
UNREASONABLE FINANCIAL PROJECTIONS

VDSCR proposes to provide ancillary services for the dental surgery cases, including crowns, X-rays, and panorex images. VDSCR states on page 22 that it will perform dental crowns and discusses dental X-ray and panoramic X-ray on pages 23 and 28. VDSCR also proposes to acquire X-ray equipment on page 177. However, the VDSCR's pro forma financial statements contain no revenue or expenses associated with these services. VDSCR includes an assumption for average charge on page 217 and an assumption for other revenue (anesthesia) on page 217 with no discussion of crowns, X-rays, or panorex images. As discussed in the assumptions within SCDP of Raleigh'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 Raleigh's dental supplies expenses includes all supplies associated with its cases. Therefore, VDSCR 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 VDSCR 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.

VDSCR 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, VDSCR should be denied.

FAILURE TO DEMONSTRATE REASONABLE DESIGN

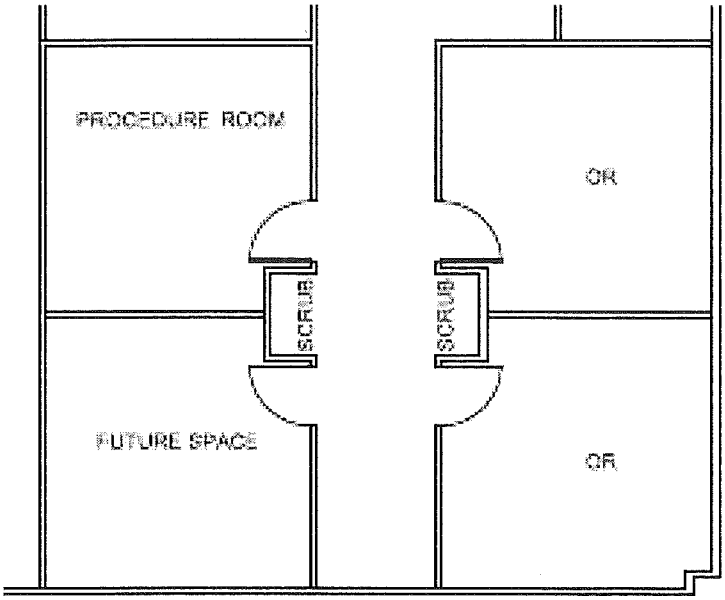
In the line drawings in Exhibit 5 of its application, VDSCR includes three operating rooms as shown in the excerpt below, not two as proposed throughout its application.



See Exhibit 5 of VDSCR.

The dental single specialty ambulatory surgery facility demonstration project allows for the development of a facility with up to two operating rooms. While VDSCR states throughout its application that it will develop two operating rooms and one procedure room, its line drawings indicate three operating rooms and no procedure room. As such, the design and construction cost estimate are unreasonable.

Further, VDSCR provides information in Exhibit 47 of its application related to development of the facility on a secondary site. In the line drawings including in Exhibit 47, two operating rooms and one procedure room are shown alongside a room of identical size labeled "Future Space" as shown in the excerpt below:



See Exhibit 47 of VDSCR.

Clearly, VDSCR intends to develop this room as shell space for a future operating or procedure room, for which it has not demonstrated the need. As such, the design of this facility is unreasonable.

VDSCR has not demonstrated that its cost and design represent the most reasonable alternative and its application should be found non-conforming with Criterion 12. As such, VDSCR should be denied.

GENERAL COMPARATIVE COMMENTS

The VDSCR and SCDP of Raleigh applications each propose to develop a dental single specialty ambulatory surgical facility demonstration project in Region 1 in response to the *2016 SMFP* need determination. SCDP of Raleigh 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 Raleigh reviewed and compared the following factors in each application:

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

SCDP of Raleigh 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 VDSCR is non-conforming to the need determination in the *2016 SMFP* for a dental single specialty ambulatory surgical facility demonstration project in Region 1. In contrast, the application submitted by SDCP of Raleigh is conforming to the need determination.

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

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

As discussed above, VDSCR will not provide open access to non-owner and non-employee oral surgeons and dentists. By its own statements in the application, VDSCR's *"primary focus will be pediatric dental surgery performed by pediatric dentists"* (page 20). This primary focus means that other oral surgeons and dentists will have less access. There can be no other interpretation.

Further, VDSCR'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 Raleigh'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.* (pages 20-21). As such, a large majority of general dentists and other dental professionals do not

currently have access to hospital-based operating rooms. VDSCR's project will not provide access to these dentists.

VDSCR 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 Raleigh*" (page 19)

While this requirement may be clinically necessary since VDSCR does not require anesthesiologist coverage for all its cases, as SCDP of Raleigh 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 to perform these cases and would be eligible to be credentialed at SCDP of Raleigh based on this expertise and not based on sedation certification. SCDP of Raleigh 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 VDSCR's model, any dental professional without the certification would be required to refer the case to another dental professional with access to the center.

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

#	*Criterion*	*VDSCR*	*SCDP of Raleigh*
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; 4.2% Charity Care and 88.5% Medicaid projected (page 163)	Conforming; 23.8% Charity Care and 47.1% Medicaid projected (page 166)

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

As discussed above, VDSCR's proposed payor mix is based on unsupported assumptions. VDSCR's projections for payor mix are based on the historical payor mix for KSA and make no attempt to adjust for WakeMed's payor mix, its largest source of referrals. This is also unreasonable for several reasons. First, as noted above, VDSCR's projections for patients by age group are unsupported. Second, KSA is an existing dental practice with several offices, none of which are in VDSCR's proposed service area. Thus, there is no relationship between the projected patient population of VDSCR and the historical patient population of KSA. VDSCR provides no information to

support the assumption that VDSCR's payor mix will be identical to KSA's historical payor mix, especially given the geographic differences in the populations.

Additionally, VDSCR 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: VDSCR Year Two

Payer	Cases			Percent
	Under 21	21 and Over	Total	
	a	*b*	*c*	*d*
Self Pay/ Indigent/ Charity	52	66	118	4.2%
Medicare / Medicare Managed Care	0	0	0	0.0%
Medicaid	2,467	50	2,518	88.5%
Commercial Insurance	53	125	178	6.3%
Managed Care	0	0	0	0.0%
Military	22	9	31	1.1%
Total	***2,594***	***251***	***2,845***	***100.0%***

See page 163 of VDSCR 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, VDSCR has overstated its charity care contribution.

Even if VDSCR'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, VDSCR's primary focus is

pediatric dental surgery on pediatric patients. VDSCR projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Raleigh projects 45.6 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.

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

#	*Criterion*	*VDSCR*	*SCDP of Raleigh*
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, VDSCR's proposed payor mix is based on unsupported assumptions and VDSCR does not provide estimated payor mix for charity care and self-pay patients separately as specified in Criterion 10-Demonstration Project.

Please note that SCDP of Raleigh 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.

Nonetheless, SCDP of Raleigh proposes to serve more pediatric patients, in total, than VDSCR. As noted above, VDSCR projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Raleigh projects 45.6 percent. However, SCDP of Raleigh proposes to serve a greater number of total patients based on its superior support from the dental community. As such, SCDP of Raleigh proposes to serve 2,696 patients under age 21 in project year two and VDSCR proposes to serve only 2,594 patients under age 21 in the same year, as shown in the tables excerpted from the application below. This is true in project years one and three as well.

SCDP of Raleigh Projected Payor Mix for Under 21

Payor	*Under 21*	*PY1*	*PY2*	*PY3*
Charity Care	13.5%	323	363	403
Self-Pay	1.6%	38	43	47
Medicaid*	67.2%	1,609	1,810	2,011
Private Insurance	17.8%	427	480	533
TRICARE	0.0%	0	0	0
Payment from Other Sources	0.0%	0	0	0
Total	**100.0%**	**2,396**	[illegible]	**2,995**

*Includes Health Choice.

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

Payer	Cases			Percent
	Under 21	21 and Over	Total	
	a	*b*	*c*	*d*
Self Pay/ Indigent/ Charity	52	66	118	4.2%
Medicare / Medicare Managed Care	0	0	0	0.0%
Medicaid	2,467	50	2,518	88.5%
Commercial Insurance	53	125	178	6.3%
Managed Care	0	0	0	0.0%
Military	22	9	31	1.1%
Total	*2,594*	*251*	*2,845*	*100.0%*

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

#	*Criterion*	*VDSCR*	*SCDP of Raleigh*
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, VDSCR utilization assumptions are unsupported by the evidence provided for a number of the specified referral sources. VDSCR's application only shows 288 cases with documented support and provides no other methodology demonstrating the utilization for its proposed project. This level of utilization is well below its projected 2,500 to 3,000 cases annually and well below the number of cases required to demonstrate the need for the two proposed operating rooms according to the demonstration project standard of 900 cases per room.

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

Documentation of Support

SCDP of Raleigh is superior to VDSCR in terms of dental professional support. On page 110 of its application, SCDP of Raleigh provides a list of 69 individual dental professionals that committed to performing or referring cases at the facility. Additionally, four clinics of Piedmont Health committed to referring patients to SCDP of Raleigh. As such, SCDP of Raleigh received support from 73 individuals and organizations committing volume to SCDP of Raleigh. In addition, another 100 letters of support from dental professionals were also included in SCDP of Raleigh's application and numerous letters of support from community agencies, universities, and more.

On page 116, of its application, VDSCR provides a list of 12 individuals and organizations that VDSCR posits will provide referrals to, or perform cases at, its facility. As noted in the Unsupported Methodology and Assumptions for Utilization section above, there are numerous issues with VDSCR's assumptions regarding these 12 individuals and organizations. Nonetheless, even if all of 12 contributed cases to VDSCR, SCDP of Raleigh has superior support from the community. Of note, VDSCR's 12 supporters include WakeMed and Advance Community Health, both of which provided similar letters of support to SDCP of Raleigh. SCDP of Raleigh did not assume any specific cases would be contributed by these organizations, unlike VDSCR, because the letters do not indicate specific referrals numbers and so these organizations are not included in the letters that count towards SCDP of Raleigh's 73 individuals and organizations committing volume to the facility but are included in VDSCR's 12 supporters committing volume.

Additionally, as evidenced in Attachments 2 and 3, VDSCR 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 2). **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 3). 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 4).

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 5, 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 overwhelming support of SCDP of Raleigh, that its proposal is preferred by the dental professional community. As noted, above, VDSCR does not provide open access to dental professionals, as required by **Criterion 2-Demonstration Project**. Similarly, VDSCR is seeking only six to eight owners, as noted in Virginia Jones' email in Attachment 5, which is likely to further limit their support and use of their facility. By comparison, SCDP of Raleigh provides open access to dental professionals and is seeking much broader ownership which has resulted in overwhelming support from dental professionals in the community.

VDSCR's misleading statements above may be an attempt to generate additional support in light of SCDP of Raleigh'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 Raleigh is superior to VDSCR in terms of support.

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

Please note that the Agency has historically included support as a comparative factor as shown in Attachment 6 which includes an excerpt from the 2011 Wake County Acute Care Bed review.

Quality of Care

VDSCR will utilize contract CRNAs under supervision of the anesthesiologists. By contrast, SCDP of Raleigh 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.

VDSCR proposes to develop dental treatment suites. These rooms will be inherently less safe due to lack of an anesthesiologist. As VDSCR states on page 35, "[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 Raleigh 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.

VDSCR proposes to develop two operating rooms, one procedure rooms, and three dental treatment suites or six rooms in total. As shown in Table VII.7 of its application on pages 169-170, VDSCR 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 0.38 FTEs per room (0.38 = 3.3 FTEs ÷ six rooms).

VDSCR 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				6
FTEs per Room				0.38

Source: VDSCR application pages 169-170.

By contrast, SCDP of Raleigh proposes to develop two operating rooms and six procedure rooms or eight rooms in total. As shown in Table VII.7 on page 175 of SCDP

of Raleigh's application, pre-, post-, and operating room staff includes 2.0 FTE RNs, 3.0 FTE Dental Assistant I and 4.0 FTE Dental Assistant II or 9.0 FTEs in total. This results in a ratio of 1.1 FTEs per room (9.0 FTEs ÷ eight rooms).

SCDP of Raleigh Dental Case Staffing

	Pre-	*Post-*	*OR*	*Total*
RN		1.00	1.00	2.00
Dental Assistant I	2.00	1.00		3.00
Dental Assistant II	1.00	1.00	2.00	4.00
Total	**3.00**	**3.00**	**3.00**	**9.00**
# of Rooms				8
FTEs per Room				**1.13**

Source: SCDP of Raleigh application page 175.

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

In summary, SCDP of Raleigh is superior to VDSCR 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.

	VDSCR	SCDP of Raleigh
UNC Department of Oral and Maxillofacial Radiology		Yes
UNC Department of Oral Pathology		Yes
Wake Technical Community College		Yes
3D Dentists		Yes
UNC School of Dentistry	Yes	Yes
DENTAC	Yes	
Total	2	5

Based on the letters of support provided in the applications, SCDP of Raleigh is **superior in terms of access for health professional training programs.**

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.

	VDSCR	SCDP of Raleigh
Percent of Total Cases to be Performed on Medicaid Recipients	88.5%	47.1%
Percent of Under 21 Cases to be Performed on Medicaid Recipients	95.1%	67.2%
Percent of 21+ Cases to be Performed on Medicaid Recipients	19.9%	30.3%

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

As shown in the table below, **SCDP of Raleigh projects to serve more Medicaid patients in total and more Medicaid patients for patients 21 years and older than VDSCR.**

	VDSCR	SCDP of Raleigh
Total Cases to be Performed on Medicaid Recipients	2,518	2,784
Under 21 Cases to be Performed on Medicaid Recipients	2,467	1,810
21+ Cases to be Performed on Medicaid Recipients	50	974

As discussed above, VDSCR's proposed payor mix is based on unsupported assumptions. Further, statements made during the public comment period by VDSCR's Chief Operating Officer, Virginia Jones, indicate that the projected payor mix for the project is unreasonable. Specifically, Ms. Virginia Jones, COO of VDSCR, stated in her email included in Attachment 5 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 VDSCR has other "true" financial projections that would provide a different comparison to SCDP of Raleigh'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.

	VDSCR	*SCDP of Raleigh*
Gross Revenue for Total Cases	$3,690,782	$11,578,794
Projected # of Cases	2,845	5,908
Average per Case	$1,297	$1,960

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

In trying to make the applications as comparable as possible the following tables illustrate each applicant's projected total revenue, which includes net patient revenue and other revenue, per case in the second year of operation, Federal Fiscal Year 2019.

	VDSCR	*SCDP of Raleigh*
Net Revenue and Other Revenue for Total Cases	$2,020,454	$6,796,002
Projected # of Cases	2,845	5,908
Average per Case	$710	$1,150

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

First, VDSCR'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 Raleigh's gross revenue includes revenue from the bundled charge which includes anesthesia.

Second, VDSCR'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 Raleigh'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 VDSCR'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 VDSCR, stated in her email included in Attachment 5 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 VDSCR has other "true" financial projections that would provide a different comparison to SCDP of Raleigh'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 Raleigh'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, VDSCR's application assumes Medicaid reimbursement to be $185 per case, which is unreasonably low, and provide no justification for that assumption as shown on page 217.

Finally, the differences in patient population between the two facilities makes a comparison unreasonable. As noted throughout these comments, VDSCR's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCR projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Raleigh projects 45.6 percent. 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.

	VDSCR	*SCDP of Raleigh*
Total Expenses for Total Cases	$1,946,425	$3,939,830
Projected # of Cases	2,845	5,908
Average per Case	$684	$667

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

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

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

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

Finally, the differences in patient population between the two facilities makes a comparison unreasonable. As noted throughout these comments, VDSCR's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCR projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Raleigh projects 45.6 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 Raleigh maintains that the VDSCR application cannot be approved as proposed. As such, SCDP of Raleigh maintains that it has the only approvable application based on its comments. Based on its comparative analysis, SCDP of Raleigh 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 1. As such, the Agency can and should approve SCDP of Raleigh.

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
Fayetteville, NC 28302-2000
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. **Misrepresentation of Available Capacity at Cape Fear Valley Health System Surgical Facilities**

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 every day 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

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 3

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 4

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 5

----- 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 6

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.