Comments on Valleygate Dental Surgery Center of the Triad

submitted by

Surgical Center for Dental Professionals of Asheville

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Surgical Center for Dental Professionals of Asheville (SCDP of Asheville) submits the following comments related to Valleygate Dental Surgery Center of the Triad's (VDSCT) application to develop a new dental surgery center. SCDP of Asheville'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 Asheville 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 VDSCT, Project ID # G-11203-16.

GENERAL COMMENTS

While the comments below will discuss the multiple specific deficiencies in the VDSCT application that necessitate its denial, SCDP of Asheville believes that an overall comparison of the applications demonstrates the clear superiority of its proposed project over that of VDSCT.

The VDSCT application has attempted to define need for the project in a way that best meets the needs of dentists who predominately serve pediatric patients, consistent with the pediatric dental practice of Knowles, Smith & Associates (KSA), the practice for VDSCT's owners. VDSCT's definition of need for this dental surgery center is consistent with the approach of Valleygate Dental Surgery Center of Raleigh (VDSCR), Project ID # J-11175-16, and Valleygate Dental Surgery Center of Fayetteville (VDSCF), Project ID # M-11176-16. SCDP of Asheville's sister facilities in Raleigh and Greenville filed detailed comments in opposition to those project enumerating their non-conformities with the CON law and with the need determination in the *2016 SMFP* for dental single specialty ambulatory surgical facility demonstration projects.

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

- "*A particular focus will be patients of pediatric dentists*" (page 27)
- "*The majority of procedures of performed at VDSCT will be pediatric dental surgeries performed by pediatric dentists*" (page 28)

In its application, VDSCT ignores the need by adult patients to access licensed surgical facilities and limits their proposed service to mostly pediatric patients. In contrast, SCDP of Asheville 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 the applications of SCDP of Asheville and its sister facilities in Charlotte, Raleigh, and Greenville who plan to perform hundreds and hundreds of adult cases per year;
- The North Carolina Board of Dental Examiners, which recently proposed new stricter rules for dentists using general anesthesia and sedation, which will effectively lower the number of general dentists who are allowed to perform sedation cases in their offices;
- VDSCT'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, VDSCT argues in its application that the dental surgery center projects should, in fact, largely be limited to pediatric patients and not a wide range of patients as required by the *2016 SMFP*, stating, "[t]*he need for dental operating rooms in the identified service areas is not entirely limited to pediatrics. However, as this application demonstrates, the majority of need is associated with the pediatric population*" (page 49). This is a clear disagreement with the requirement for a wide range of access by the dental ambulatory

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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.

surgery center demonstration projects. SCDP of Asheville 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 Asheville's application, "*unlike a large majority of general dentists or other dental subspecialties, pediatric dentists must complete a required two to three year residency for training specific to providing care to patients in an operating room setting with the aid of an anesthesiologist. As a practical matter due to this distinction in training, while some hospitals do extend privileges to general dentists who have general practice residency training, hospital bylaws generally include provisions to permit the privileging of pediatric dentists, but exclude general dentists and other dental subspecialties*. (page 19). As such, 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.

Moreover, VDSCT's assertion that few adults require care in a licensed facility is not supported. First, Valleygate Dental Surgery Center of Raleigh, which shares owners with VDSCT, submitted a certificate of need application for a dental single specialty ambulatory surgical facility demonstration project in Region 1 and assumed that its largest referral source will be WakeMed, which provides 22 percent of its dental surgery cases to adults (please see Surgical Center for Dental Professionals of Raleigh's comments on VDSCR). Thus, KSA is or should be aware that current providers serve a substantial number of adult patients. Similarly, the organizations in the bulleted list above recognize the need for adult and pediatric patients. Finally, the North Carolina Board of Dental Examiners' focus on changing the rules for sedation is driven by a concern with safety in office settings for adults and children. Thus, VDSCT's assertion that the 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.

VDSCT further limits access to its facility through the facility requirements for its practitioners by requiring "*that all of its dentists and oral surgeons who seek credentials at the facility either hold and maintain sedation permits with the North Carolina State Board of Dental Examiners or have completed an approved post-graduate dental residency program"* (page 25). SCDP of Asheville believes this requirement will limit access to the VDSCT's facility without any benefits to patients. Only 500 of the 5,000 dentists statewide, or 10 percent hold a sedation permit. Based on its experience with the State Dental Board's credentialing process for sedation permits, SCDP of Asheville firmly believes that there is nothing in the process of gaining a sedation permit that prepares a dentist to work around an anesthetized patient. [3] By contrast, SCDP of Asheville's credentialing process and training will prepare the dental professionals who utilize its facility to work around

[3] In fact, as discussed below, the NC Board of Dental Examiners' web site indicates that only three of the five dentists supporting the VDSCT application currently are qualified to perform dental sedation.

an anesthetized patient far better than a dentist who only possesses a sedation permit, particularly as board-certified anesthesiologists, not CRNAs or the dental professional, will be responsible for the sedation and/or anesthesia of all patients at SCDP of Asheville.

General dentists who lack the sedation permit or have not sought residency training are able to expertly perform these cases and would be eligible to be credentialed at SCDP of Asheville based on their expertise. SCDP of Asheville 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 VDSCT's model, any dental professional that does not meet its requirements would be required to refer the case to another dental professional with access to the surgery center.

Again, VDSCT'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 Asheville does not believe that a facility which limits access to approximately 10 percent of the dental providers in the state is an effective option for this demonstration project.

Further, VDSCT'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. VDSCT'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, VDSCT's application does not meet the requirements of the demonstration and should be found non-conforming with Criterion 1. As such, VDSCT should be denied.

APPLICATION-SPECIFIC COMMENTS

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

(1) Unsupported methodology and assumptions for utilization;
(2) Unsupported methodology and assumptions for age and payor mix; and,
(3) Unreasonable financial projections.

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

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR UTILIZATION

On pages 131-134 of its application under the heading "Part 1: Utilization Projections for Entire Facility", VDSCT provides data that fails to support its utilization methodology.

On page 132 of its application, VDSCT states "*Table IV.2 contains a list of the dentists in the eleven county service area, who, to date, have indicated interest in bringing cases to VDSCT.*" Following that VDSCT provides a summary table of the estimated volume associated with these dental professionals:

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

Dentists	Specialty	Low Estimate of Cases	High Estimate of Cases
Gina Spangler, DDS	Pediatric	120	180
Gail Rohlfing, DDS	Pediatric	72	96
Kate Lambert, DDS	Pediatric	120	180
Sona Isharani, DDS	Pediatric	360	360
Matt Applebaum, DMD	Pediatric	60	240
Stephanie Lindsay, DDS, MS	Pediatric	84	120
Total		***816***	***1,176***

Source: Estimates provided by dentists who propose to utilize the facility.
Note: All of these proposed user dentists currently meet the training requirements in VDSCT's credentialing criteria

However, Table IV.2 misrepresents the letters of support included in VDSCT's application. First, the application does not include a letter from Matt Applebaum, DMD despite his inclusion in the table above indicating Dr. Applebaum supports the project and expects to perform 60 to 240 cases annually at the proposed facility. Second, Sona Isharani's letter of support in Exhibit 18 and excerpted below provides an estimate of five to 20 cases per month, or 60 to 240 cases annually, not 360 cases annually as indicated in Table IV.2 above.

I am a Peds DDS, practicing in Guilf County.

☑ I/we fully support this proposed center

☑ I fully support the proposed center and expect to perform 5-20 cases there a month, once the facility is operational.

☑ I or my group currently has active staff privileges at Cone hospital

This is an excellent proposal for a much needed service. I understand the current owners of Knowles, Smith and Associates (KSA), and possibly other dentists will establish the surgery centers. KSA is an organization that has a long-standing reputation for quality dental care and as community partners. I urge the Division of Health Service Regulation to approve their application.

Sincerely,

Signature

Sona Isharani

2707C Piedale Road GSO NC 27408

(Print name and address)

Name: sona Isharani Address:

The table below provides an accurate revision of VDSCT Table IV.2 which shows a range of 456 to 816 cases annually, rather than the 816 to 1,176 cases stated in the application.

	Estimated Volume from Table IV.2 (page 132)		*Revised Volumes Based on Letters*	
	Low Estimate	*High Estimate*	*Low Estimate*	*High Estimate*
Gina Spangler, DDS	120	180	120	180
Gail Rohlfing, DDS	72	96	72	96
Kate Lambert, DDS	120	180	120	180
Sona Isharani, DDS	360	360	60	240
Matt Applebaum, DMD	60	240	0	0
Stephanie Lindsay, DDS, MS	84	120	84	120
Total	**816**	**1,176**	**456**	**816**
Difference from Estimate in Application			**-44%**	**-31%**

As shown, the revised volumes associated with VDSCT's supporting dental professionals are 31 to 44 percent less than what is represented in the application.

On page 133, VDSCT states that it "*reasonably forecasts an initial market share of 17.5 percent of the projected need for dental surgery cases, increasing to 22 percent of the need served in year three of the proposed project.*" VDSCT provides no quantitative basis for this market share assumption. There is no explanation, at all, for why 17.5 to 22 percent is assumed for VDSCT's share.

Similarly, VDSCT provides no quantitative justification assumes that its market share of oral surgery cases will be 39.5 to 48 percent, stating "[t]*o be conservative, the applicant estimates that only 100 oral surgery cases by the third year of operation, or 48 percent of the need for oral surgery cases in a dental ASC in the service area in 2010, will be completed by VDSCT . . . assume a market share of 39.5 percent in 2018*" (page 135). There is no explanation, at all, for why 39.5 to 48 percent is assumed for VDSCT's share of oral surgery, or why that is reasonable given then lower market share assumed for dental surgery cases.

VDSCT also states in its application that its facility will serve "*patients classified as ASA class IV or lower*" (page 27). SCDP of Asheville has significant concerns about the safety of treating patients classified as ASA III and IV outside of a hospital setting. As VDSCT states on page 138, "[c]*lassification as ASA level III and IV means a patient must have severe systemic disease or the possibility of surgical complications.*" SCDP of Asheville believes that VDSCT's utilization projections are overstated based on the inclusion of ASA III and IV patients that would not be appropriate for care in an ambulatory surgery center.

Finally, as noted above, VDSCT requires that "*that all of its dentists and oral surgeons who seek credentials at the facility either hold and maintain sedation permits with the North Carolina State Board of Dental Examiners or have completed an approved post-graduate dental residency program*" (page 25). However, VDSCT does not demonstrate that it notified its supporting dentists of these requirements. Exhibit 18 includes copies of VDSCT's electronic communication regarding its project which do not describe the credentialing requirements in its letter of solicitation. As such, it is unclear whether its supporting dentists would or could meet these requirements. If they do not meet these requirements, they would be unable to perform cases in the ASC as proposed.

VDSCT states in a note under Table IV.2 that "[a]*ll of these proposed user dentists currently meet the training requirements in VDSCT's credentialing criteria*" (page 132). However, data from the North Carolina Dental Board and summarized in the table below casts doubt on this statement. The According to the North Carolina Dental Board records (see Attachment 1), only of two VDSCT's five supporting dentists have a sedation permit (excluding Matt Applebaum, who did not provide a letter of support).

	Anesthesia Permit	*Sedation Permit*
Gina Spangler, DDS	No	No
Gail Rohlfing, DDS	No	No
Kate Lambert, DDS	No	Yes
Sona Isharani, DDS	No	No
Stephanie Lindsay, DDS, MS	No	Yes
Total	**0**	**2**

While pediatric dentists are likely to have completed a post-graduate dental residency program, VDSCT has not demonstrated this is the case for general dentists. Further, the lack of a sedation permit would preclude these dentists from directing CRNAs. In order to legally direct a CRNA during a procedure, as VDSCT proposes will occur in its treatment rooms, the dentist must have a permit equal to or greater than the CRNA. Thus, the three VDSCT supporting dentists that lack permits would be unable to direct CRNAs. Given these factors, it is unclear whether these supporting dentists could practice at VDSCT given its credentialing requirements, which results in a lack of support for its utilization projections.

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

UNSUPPORTED METHODOLOGY AND ASSUMPTIONS FOR AGE AND PAYOR MIX

VDSCT's projections for the percent of patients by age group and by payor class are unsupported and unreasonable. As VDSCT states on page 174 of its application, it determined the number of children and adult cases in year two by multiplying its "*total projected dental cases served in year two from Table IV.5 by the estimated percent of persons over 21 (adults) in year two from Table IV.6 (8.82 percent).*" As shown in Table IV.6 on page 136, 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. VDSCT assumes that the age mix of its patients, which are specific to its proposed service area, will be identical to the age mix of Medicaid patients statewide. This is unreasonable. VDSCT provides no information to indicate that its age mix will be identical to that of the Medicaid population statewide. VDSCT provides no information to indicate that the age mix of patients in the Guilford County area is identical to the Medicaid population statewide.

Similarly, VDSCT's assumed percentages of charity care and self pay patients are based on statewide data:

> *The 3.64 percent charity and 1.60 percent self-pay is an estimate derived by from* [sic] *US Census information. According to the US Census Bureau, 5.2 percent of North Carolinians under 18 are uninsured. Census data also shows that roughly 70 percent of uninsured individuals live in households with incomes below $50,000. Assume that charity percentage for the under 21 patients to be 70 percent of 5.2 (5.2 * 70% = 3.64). Assume the remainder is non charity, self-pay (5.2 – 3.6 = 1.60)*
>
> See page 175.

VDSCT again assumes that its patient population, which is specific to its proposed service area, will be identical to the statewide population. VDSCT further assumes that the percent of the state population without healthcare insurance (the uninsured) is equal to percent of state population within dental insurance. In fact, dental insurance is not as commonly held by patients as healthcare insurance. Therefore, patient payor mix for dental patients is different than for service covered by healthcare insurance, particularly with regard to self-pay patients who have the financial means to pay for dental care and choose to do so out-of-pocket. VDSCT does not provide information to indicate that the percentage of patients without dental insurance in Guilford County is identical to percentage of patients without healthcare insurance statewide and that its self-pay assumptions are reasonable.

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

Of note, VDSCT's application does provide assumptions for the charity care and self-pay patients separately whereas previous applications submitted by Knowles, Smith & Associates for dental ambulatory surgery centers in Raleigh (J-11175-16) and Fayetteville (M-11176-16) that are currently under review failed to provide both charity care and self-pay data. SCDP of Asheville believes that the failure in these prior applications to provide charity care and self-patients separately demonstrates non-conformity with Criteria 5 and 13(c) in addition to non-conformity with the dental single specialty ambulatory surgical facility demonstration project criteria. VDSCT's inclusion of this information should be regarded as confirmation that Knowles, Smith & Associates also believes that its prior applications are non-conforming.

Further, VDSCT's application states that the "*Single Specialty Dental Demonstration Project Criterion #10 <u>requires</u> that applicant provides* [sic] *a breakdown of the projected number of patients for the first three full federal fiscal years of the project*" (page 179). Neither VDSCR nor VDSCF provided this information. VDSCT's clear acknowledgement of this requirement demonstrates that VDSCR and VDSCF failed to provide required information and should be found non-conforming.

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

UNREASONABLE FINANCIAL PROJECTIONS

VDSCT proposes to provide ancillary services to the dental surgery cases, including crowns and panorex x-ray. VDSCT discusses the use of crowns on page 62 as part of the treatment of early childhood caries (ECC), which VDSCT proposes to address at its facility and states on page 30 that it will provide panorex X-ray. The equipment list in Section VIII, page 193 of the application includes X-ray equipment. However, the VDSCT's pro forma financial statements contain no revenue or expenses associated with these services. VDSCT includes an assumption for average charge on page 233 which includes a facility fee and anesthesia charge with no discussion of crowns or panorex images. As discussed in the assumptions within SCDP of Asheville'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 Asheville's dental supplies expenses includes all supplies associated with its cases. Therefore, VDSCT 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 VDSCT 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.

Of note, VDSCT's assumed reimbursement differs significantly from prior information submitted by its owner, KSA, in the VDSCR and VDSCF applications. The table below compares the average net revenue which includes facility and anesthesia charges for procedure rooms for VDSCT, VDSCR, and VDSCF in project year two. Please note that no oral surgery cases are provided in procedure rooms in any of these projects, thus the table below provides an accurate comparison of procedure room charges and reimbursement. Further, no inflation is assumed in revenue per case in any of the applications, which also supports the accuracy of this comparison.

	VDSCR	*VDSCF*	*VDSCT*	*VDSCT % Difference from VDSCR*	*VDSCT % Difference from VDSCF*
Net Revenue and Other Revenue for Procedure Room Cases	$498,446	$1,121,126	$553,898		

Projected # of Procedure Room Cases	706	1,662	641		
Average Net Revenue per Procedure Room Case	**$706**	**$675**	**$864.12**	22.4%	28.1%

Source: VDSCR, Procedure Room Form C, page 208; VDSCF, Procedure Room Form C, page 231; VDSCT, Procedure Room Form C, page 224.

As shown above, VDSCT projects 22 to 28 percent higher reimbursement per procedure room case than two dental surgery center projects previously submitted by VDSCT's owner, KSA. VDSCT provides no discussion of why its reimbursement would be so much greater than these two other facilities.

Similarly, VDSCT projects significantly higher reimbursement for dental surgery in operating rooms. As shown on page 233 and excerpted below, VDSCT provides operating room dental surgery reimbursement by payor class:

Combined Anesthesia + Facility Fee Gross and Net Revenue by Payer

	OMS Volumes Year Three	Dental Volumes Year Three	Gross Revenue	Average Charge (c)	Dental Reimbursement (a)
Charity	5	104	$ 184,215	$ 1,701	$ 75
Self Pay	2	45	$ 80,581	$ 1,699	$ 800
Medicare	-	-	$ -		$ -
Medicaid	8	2,253	$ 3,637,282	$ 1,609	$ 735
Commercial	85	362	$ 919,465	$ 2,058	$ 1,500
Managed Care	-	-	$ -		$ -
Military	0	26	$ 43,081	$ 1,619	$ 1,089
Total	100	2,790	$ 4,864,623		

Based on the assumed dental reimbursement per payor and the projected operating room dental volumes, VDSCT projects $814 in net revenue per operating room dental surgery case as calculated below.

	Dental Surgery Volume	*Dental Surgery Reimbursement per Case*	*Total Reimbursement*
Charity	104	$75	$7,800
Self Pay	45	$800	$36,000
Medicaid	2,253	$735	$1,655,955
Commercial	362	$1,500	$543,000
Military	26	$1,089	$28,314
Total	**2,790**	**$814**	**$2,271,069**

By comparison, VDSCR and VDSCF project only $698 and $676 net revenue per dental surgery operating room case as shown below.

	VDSCR	*VDSCF*	*VDSCT*	*VDSCT % Difference from VDSCR*	*VDSCT % Difference from VDSCF*
Net Revenue and Other Revenue for Operating Room Cases	$1,352,085	$1,269,457	$2,271,069		
Projected # of Procedure Room Cases	1,938	1,879	2,790		
Average Net Revenue per Operating Room Case	**$698**	**$676**	**$814**	**16.7%**	**20.5%**

Source: VDSCR, Operating Room Form C, page 205; VDSCF, Operating Room Form C, page 228; VDSCT, from dental surgery operating room case reimbursement assumptions on page 233, calculations in prior table.

As such, VDSCT projects 17 to 21 percent higher reimbursement per operating room dental surgery case than VDSCR and VDSCF, respectively. VDSCT provides no discussion of why its reimbursement would be so much greater than these two other facilities.

Of note, SCDP of Asheville's communications with Dr. Mark Casey, Dental Director of the NC Division of Medical Assistance have indicated a Medicaid reimbursement rate for dental ambulatory surgery facility to be consistent with VDSCT's assumed reimbursement of $736 per Medicaid case. VDSCF and VDSCR's application assume Medicaid reimbursement to be $175 per case. It is unclear whether VDSCT recognized that projected Medicaid reimbursement for VDSCF and VDSCR was is unreasonably low. At any rate, VDSCT provides no explanation for that change in this application.

Finally, SCDP of Asheville could not accurately compare VDSCT's gross revenue per operating room or procedure room case to these two prior projects because VDSCT's gross charges includes an anesthesia charge and VDSCR and VDSCF's gross charges do not included anesthesia. In the VDSCR and VDSCF financial statements, anesthesia revenue is included as other revenue (after deductions and net patient revenue on the income statement) which is only reimbursement and not the associated charge.

VDSCT 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, VDSCT should be denied.

GENERAL COMPARATIVE COMMENTS

The VDSCT and SCDP of Asheville applications each propose to develop a dental single specialty ambulatory surgical facility demonstration project in Region 4 in response to the *2016 SMFP* need determination. SCDP of Asheville 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 Asheville reviewed and compared the following factors in each application:

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

SCDP of Asheville 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 VDSCT is non-conforming to the need determination in the *2016 SMFP* for a dental single specialty ambulatory surgical facility demonstration project in Region 2. In contrast, the application submitted by SDCP of Asheville is conforming to the need determination.

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

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

As discussed above, VDSCT will not provide open access to non-owner and non-employee oral surgeons and dentists. By its own statements in the application, VDSCT's "*particular focus will be patients of pediatric dentists*" (page 27).

This focus means that other oral surgeons and dentists will have less access. There can be no other interpretation.

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

VDSCT further limits access to its facility for general dentists and it will require "*all of its dentists or oral surgeons who seek credentials at the facility either hold and maintain sedation permits with the North Carolina State Board of Dental Examiners or have completed an approved post-graduate dental residency program*" (page 25).

Although this requirement may be clinically necessary since VDSCT does not require anesthesiologist coverage for all its cases, as SCDP of Asheville does, it limits access to the facility. Only approximately 500 of the 5,000 dentists statewide, or only 10 percent, hold sedation permits. General dentists who lack this certification are able to expertly perform these cases and would be eligible to be credentialed at SCDP of Asheville based on their expertise and not based on sedation certification. SCDP of Asheville 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 VDSCT's model, any dental professional without the certification would be required to refer the case to another dental professional with access to the center.

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

#	*Criterion*	*VDSCT*	*SCDP of Asheville*
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; 3.75% Charity Care and 78.23% Medicaid projected (page 174)	Conforming; 4.2% Charity Care and 52.0% Medicaid projected (page 178)

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

As discussed above, VDSCT's proposed payor mix is based on unsupported assumptions. VDSCT's projections for patients by age group are unsupported, therefore, their Medicaid payor mix projections are unsupported. Further, VDSCT's projections for charity care are based on statewide healthcare insurance rates, not dental insurance rates.

Even if VDSCT'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, VDSCT's primary focus is pediatric dental surgery on pediatric patients. VDSCT projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Asheville projects 32.5 percent. This difference in patient population results in differences in payor mix, and, as will be discussed later, revenues and expenses. As such, a reasonable comparison cannot be made.

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

#	*Criterion*	*VDSCT*	*SCDP of Asheville*
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, VDSCT's proposed payor mix is based on unsupported assumptions. **VDSCT's application does not meet the requirements of Criterion 10-Demonstration Project. As such, VDSCT is comparatively inferior to SCDP of Asheville.**

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

#	*Criterion*	*VDSCT*	*SCDP of Asheville*
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, VDSCT's utilization assumptions are unsupported.

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

Documentation of Support

SCDP of Asheville is superior to VDSCT in terms of dental professional support. On page 118 of its application, SCDP of Asheville provides a list of 15 individual dental professionals in the Asheville area in support of its project (three committed to perform performing at, or refer cases to, the facility, and 12 supported the project, and in some cases expressed interest in investing in it).

In Exhibit 18 of its application, VDSCT provides support letters from list of eight pediatric dentists and oral surgeons in support of its project. As noted in the Unsupported Methodology and Assumptions for Utilization section above, there are issues with VDSCT's assumptions regarding its dental professionals. SCDP of Asheville has superior support from the community.

Additionally, as evidenced in Attachment 2 and 3, VDSCT 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 VDSCT, 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 VDSCT's owners, it is unclear whether any of the support for these projects is reliable. 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 VDSCT has 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 support of SCDP of Asheville, that its proposal is supported by the dental professional community. As noted, above, VDSCT does not provide open access to dental professionals, as required by **Criterion 2-Demonstration Project**. By comparison, SCDP of Asheville provides open access to dental professionals and is seeking much broader ownership which has resulted in support from dental professionals in the community.

In summary, SCDP of Asheville is superior to VDSCT in terms of support.

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.

Geographic Access

SCDP of Asheville proposes to locate its facility in Buncombe County and VDSCT proposes to locate its facility in Guilford County. SCDP of Asheville is the superior to VDSCT in terms of geographic access as discussed below.

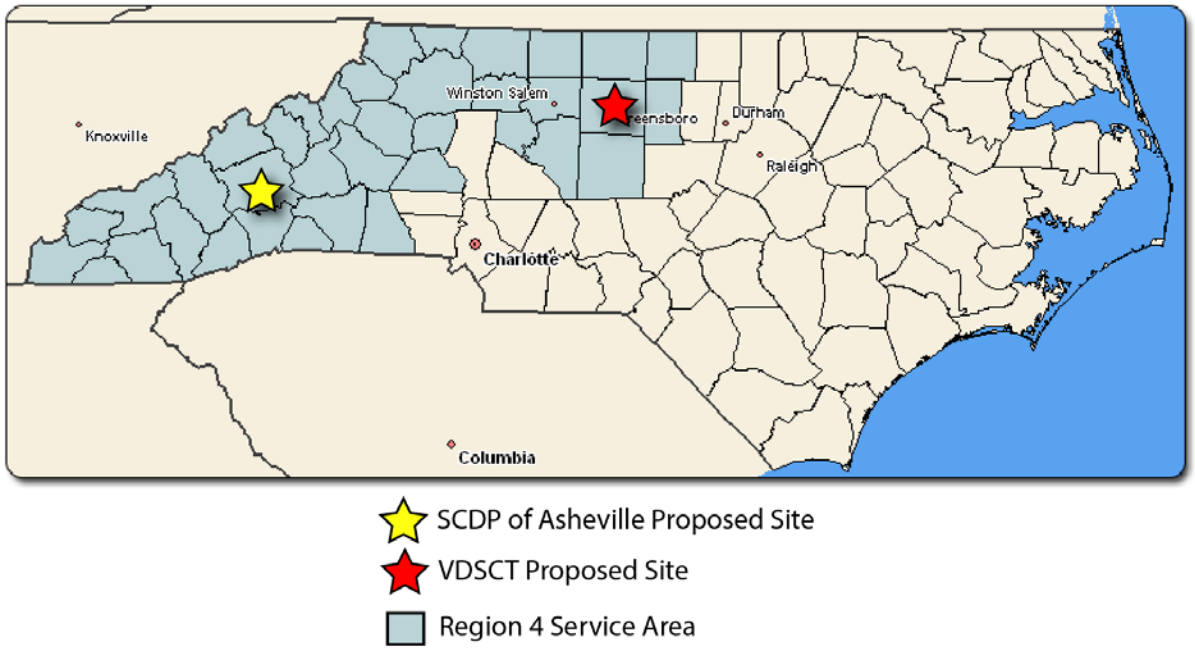
As noted on pages 81-87 of its application, SCDP of Asheville believes its proposed location is the most effective alternative for a dental single specialty ambulatory surgical facility demonstration project in Region 4. SCDP of Asheville's proposed location is ideal for numerous reasons including the presence of hospitals in Forsyth and Guilford counties that perform a significant volume of oral surgery. Moreover, there is a significant surplus of operating room capacity in Guilford County, indicating that access to operating rooms is not restricted. According to Table 6B in the *2016 SMFP*, Guilford County has an operating room surplus of 30.89 rooms, by contrast, Buncombe County, the location for SCDP of Asheville has an operating room surplus of only 4.08 rooms. Thus, it is much more unlikely that dental surgery cases would not be able to be scheduled in Guilford County, given the highly underutilized state of the operating rooms there, and, in fact, the volume of oral surgery cases performed in operating rooms in Guilford County demonstrates that substantial access for these cases exists.

Further, SCDP of Asheville believes that these counties around the Triad are more proximal to Regions 1 and 2, each of which has its own need determination through which a facility will likely be developed. In addition, the location of a facility in the eastern part of the region will impede access to the population in the western portion of the region, which includes counties that have typically been underserved.

Residents of Asheville and other areas of western North Carolina face additional barriers to accessing care than residents of other counties within Region 4. This is particularly true when compared to other populous areas that could likely support a dental ASC within the region such as the Triad. For instance, it is difficult to travel from Asheville to Charlotte due to the lack of direct Interstate access. This is not the case for residents of cities within the Triad who benefit from the direct accessibility of Interstate 85 and Interstate 40 which provide easy routes to Charlotte and Raleigh. While it is difficult for residents of Asheville to travel to central and eastern North Carolina, it is even more difficult for residents who live west of Asheville to do so. Residents of western North Carolina live in the mountains which create a natural geographic barrier that makes traveling more difficult. Not only are these counties located further away from central and eastern North Carolina in terms of mileage but additional travel time is another factor inhibiting easy access to services offered within the Charlotte, Raleigh, and Greenville regions. Even if the mileage is the same, residents of western North Carolina experience lengthier commutes due to the mountainous terrain and twisting roadways that require slower speeds. Variable weather conditions, particularly during the winter months, also adversely impact the ability of western North Carolina residents to access services. SCDP of Asheville believes that its proposed location will provide access to residents of western North Carolina who are typically underserved due to these geographic barriers.

Given these geographic barriers in Region 4, it is important to locate the proposed facility in an area that is accessible by residents of the western counties, such as Cherokee, while also remaining accessible to residents of the Region. SCDP of Asheville's proposed location is less than two hours from both Cherokee and Cleveland counties. Although the proposed facility will be located further away from the eastern portions of this region, these counties have greater proximity to other markets of the state, such as Region 1 and Region 2. This is not to say that patients residing in these counties will not have access to the proposed facility in Asheville, but they may have fewer barriers to access given their location in the Piedmont region of the state than those who reside in western North Carolina.

By comparison, VDSCT's location, in Guilford County, will not provide proximate access to residents of Region 4's western. As shown in the map below, VDSCT's proposed facility is not centrally located in Region 4 and is closer to Region 1 and Region 2 where other dental single specialty ambulatory surgical facility demonstration projects may be developed.



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

Distance in Miles Between Proposed Facilities

	VDSCR	*SCDP of Raleigh*
VDSCT	93 miles	86 miles
SCDP of Asheville	251 miles	244 miles

VDSCT's location is also inferior given the two dental single specialty ambulatory surgical facility demonstration projects for Region 2 propose to develop facilities in Mecklenburg County, Carolinas Center for Ambulatory Dentistry (CCAD) in Charlotte and SCDP of Charlotte in Charlotte. As shown in the table below, VDSCT will be located closer to both CCAD and SCDP of Charlotte than SCDP of Asheville.

Distance in Miles Between Proposed Facilities

	CCAD	*SCDP of Charlotte*
VDSCT	92 miles	92 miles
SCDP of Asheville	125 miles	125 miles

SCDP of Asheville believes that placing the Region 4 facility further from the Region 1 and 2 dental facilities, particularly with greater access to the western mountainous areas of North Carolina, will provide the greatest geographic access for patients.

In summary, SCDP of Asheville is superior to VDSCT in terms of geographic access.

Quality of Care

VDSCT will utilize contract CRNAs under supervision of the dental anesthesiologists. By contrast, SCDP of Asheville 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.

VDSCT proposes to develop dental treatment suites. These rooms will be inherently less safe due to lack of an anesthesiologist. As VDSCT states on page 31, "[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. This is provides no increase in safety compared to the current practices in North Carolina which allow a credentialed dentist to provide sedation in their offices. By contrast, SCDP of Asheville 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.

VDSCT proposes to develop two operating rooms, two procedure rooms, and one active dental treatment suite, or five rooms in total. As shown in Table VII.7 of its application on pages 198-202, VDSCT pre-, post-, and operating room staff includes 2.27 FTE RNs and 0.55 dental assistants or 2.82 FTEs in total excluding CRNAs. This results in a ratio of 0.56 FTEs per room (0.56 = 2.82 FTEs ÷ five rooms).

VDSCT Dental Case Staffing

	Pre-	*Post-*	*OR*	*Total*
RN	1.13	1.13		2.27
Surgical Technician			0.55	0.55
Total	**1.13**	**1.13**	**0.55**	**2.82**
# of Rooms				**5**
FTEs per Room				**0.56**

Source: VDSCT application pages 182-186.

By contrast, SCDP of Asheville proposes to develop two operating rooms and two procedure rooms, or four rooms in total. As shown in Table VII.7 on page 183 of SCDP of Asheville's application, pre-, post-, and operating room staff includes 1.5 FTE RNs, 1.5 FTE Dental Assistant I and 2.0 FTE Dental Assistant II or 5.0 FTEs in total. This results in a ratio of 1.25 FTEs per room (5.0 FTEs ÷ four rooms).

SCDP of Asheville Dental Case Staffing

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

Source: SCDP of Asheville application page 187.

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

As noted above, VDSCT also states in its application that its facility will serve "*patients classified as ASA class IV or lower*" (page 22). SCDP of Asheville has significant concerns about the safety of treating patients classified as ASA III and IV outside of a hospital setting. As CCAD states on page 138, "[c]*lassification as ASA level III and IV means a patient must have severe systemic disease or the possibility of surgical complications.*" SCDP of Asheville believes this risk is further exacerbated by VDSCT's lower levels of staffing, its use of CRNAs, and its policy of permitting dentists to direct sedation on their own cases.

In summary, SCDP of Asheville is superior to VDSCT 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.

<u>Access for Health Professional Training Programs</u>

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.

	VDSCT	*SCDP of Asheville*
ECU School of Dental Medicine	Yes	Yes
UNC Department of Oral and Maxillofacial Radiology		Yes
UNC Department of Oral Pathology		Yes
3D Dentists		Yes
MAHEC		Yes
Total	**1**	**5**

Based on the letters of support provided in the applications, **SCDP of Asheville 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.

	VDSCT	*SCDP of Asheville*
Percent of Total Cases to be Performed on Medicaid Recipients	78.1%	52.0%
Percent of Under 21 Cases to be Performed on Medicaid Recipients	82.7%	38.5%
Percent of 21+ Cases to be Performed on Medicaid Recipients	33.1%	67.1%

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

As discussed above, VDSCT's proposed payor mix is based on unsupported assumptions. Further, statements made prior to the submission of VDSCT's application by KSA's Chief Operating Officer, Virginia Jones, indicate that the projected payor mix for the project is unreasonable. Specifically, Ms. Virginia Jones, stated in her email included in Attachment 5 that the CON financial projections for a dental ASC 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 VDSCT's owners have other "true" financial projections that would provide a different comparison to SCDP of Asheville'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, 2019.

	VDSCT	***SCDP of Asheville***
Gross Revenue for Total Cases	$4,656,449	$5,305,882
Projected # of Cases	2,767	2,710
Average per Case	$1,683	$1,958

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

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

	VDSCT	***SCDP of Asheville***
Net Revenue and Other Revenue for Total Cases	$2,463,905	$3,547,772
Projected # of Cases	2,767	2,710
Average per Case	$890	$1,309

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

First, as noted above, VDSCT's gross revenue and net revenue assumptions are not consistent with previous assumptions provided by KSA. Given these inconsistencies, SCDP of Asheville believes VDSCT's assumptions are unsupported.

Second, VDSCT'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 Asheville'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 prior to submission of VDSCT's application by KSA's Chief Operating Officer, Virginia Jones, indicate that the projected payor mix and revenues for the project is unreasonable. Specifically, Ms. Virginia Jones, stated in her email included in Attachment 5 that the CON financial projections for a dental ASC 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 VDSCT's owners have other "true" financial projections that would provide a different comparison to SCDP of Asheville's application. Based on these factors, the projected payor mix shown in the application cannot be used as a basis for comparison.

Finally, the differences in patient population between the two facilities makes a comparison unreasonable. As noted throughout these comments, VDSCT's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCT projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Asheville projects 32.5 percent. This difference in patient population results in differences in the revenues. The revenue (and expense) of restoring permanent teeth is greater than primary teeth (or "baby teeth") based on the instruments and supplies required. As such, a reasonable comparison cannot be made.

Expenses

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

	VDSCT	***SCDP of Asheville***
Total Expenses for Total Cases	$2,167,823	$2,968,845
Projected # of Cases	2,767	2,710
Average per Case	$783	$1,096

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

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

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

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

Finally, the differences in patient population between the two facilities makes a comparison unreasonable, particularly, for Medicaid. As noted throughout these comments, VDSCT's primary focus is pediatric dental surgery surgery on pediatric patients. VDSCT projects 91.2 percent of its total cases to be pediatric patients whereas SCDP of Asheville projects 32.5 percent. This difference in patient population results in differences in the expenses. The revenue (and expense) of restoring permanent teeth is greater than primary teeth (or "baby teeth") based on the instruments and supplies required.

As such, a reasonable comparison cannot be made.

SUMMARY

As noted previously, SCDP of Asheville maintains that the VDSCT application cannot be approved as proposed. As such, SCDP of Asheville maintains that it has the only approvable applications based on its comments. Based on its comparative analysis, SCDP of Asheville 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 4. As such, the Agency can and should approve SCDP of Asheville.

Attachment 1

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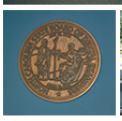

search results

DENTISTS

Dr. Gina Shropshire Spangler
City : WINSTON-SALEM
State : NC
Board Action : N
Anesthesia: N
View Disciplinary Actions

License # : 6270 (Licensed Dentist)
License Issued : 6/23/1993
Expiration : 3/31/2017
Status : Good Standing
Sedation: N

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Functions of the Board of Dental Examiners

- The administration of licensure examinations for dentists and dental hygienists
- The promulgation of rules and enforcement of laws and regulations governing the practice of dentistry and dental hygiene in this state
- The issuance and renewal of licenses to dentists and dental hygienists

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DENTISTS

Dr. Gail Kaye Rohlfing
City : Winston-Salem
State : NC
Board Action : N
Anesthesia: N
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License # : 6463 (Licensed Dentist)
License Issued : 6/16/1995
Expiration : 3/31/2017
Status : Good Standing
Sedation: N

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info@ncdentalboard.org

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search results

DENTISTS	
Dr. Katherine Stuart Donovan Lambert	**License # :** 9142 (Licensed Dentist)
City : Winston-Salem	**License Issued :** 6/6/2011
State : NC	**Expiration :** 3/31/2017
Board Action : N	**Status :** Good Standing
Anesthesia: N	**Sedation:** Y
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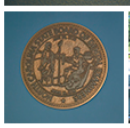

search results

DENTISTS	
Dr. Sona J. Isharani	**License # :** 7444 (Licensed Dentist)
City : GREENSBORO	**License Issued :** 6/19/2002
State : NC	**Expiration :** 3/31/2017
Board Action : N	**Status :** Good Standing
Anesthesia: N	**Sedation:** N
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Filing Complaint
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Meeting Announcements
Management Arrangements
Forms
Professional Corporation
Online Examination
Board Newsletter

search results

DENTISTS	
Dr. Stephanie P. Lindsay	**License # :** 7018 (Licensed Dentist)
City : HIGH POINT	**License Issued :** 6/23/1999
State : NC	**Expiration :** 3/31/2017
Board Action : N	**Status :** Good Standing
Anesthesia: N	**Sedation:** Y
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- The promulgation of rules and enforcement of laws and regulations governing the practice of dentistry and dental hygiene in this state
- The issuance and renewal of licenses to dentists and dental hygienists

info@ncdentalboard.org

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, 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.