

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2016
Findings Date: October 4, 2016
Project Analyst: Gregory F. Yakaboski
Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: Q-11171-16
Facility: Surgical Center for Dental Professionals of Greenville
FID #: 160153
County: Pitt
Applicant: Surgical Center for Dental Professionals of Greenville, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Pitt County pursuant to the demonstration project in the 2016 SMFP

Project ID #: M-11176-16
Facility: Valleygate Dental Surgery Center of Fayetteville
FID #: 160152
County: Cumberland
Applicants: Valleygate Dental Surgery Center of Fayetteville, LLC
VFD Real Estate Partners, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative

limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC-SCDP Greenville
C- Valleygate

The 2016 State Medical Facilities Plan (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which include Cumberland and Pitt counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

In response to petitions from Knowles, Smith & Associates and Triangle Implant Center, an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Demonstration Project (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state exemplifies the access and value Basic Principles by preventing a single area from having a concentration of dental OR facilities. The Project establishes a special need determination for up to four new separately licensed dental single specialty ambulatory surgical facilities with up to two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the four following regions:

- *Region 1: HSA IV*
- *Region 2: HSA III*
- *Region 3: HSA V and HSA VI*
- *Region 4: HSA I and HSA II*

Applicants shall demonstrate in the certificate of need application that the proposal will meet each criterion set forth below:

Table 6D: Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

CRITERION		BASIC PRINCIPLE AND RATIONALE
1	<i>The application shall contain a description of the percentage ownership interest in the facility by each oral surgeon and dentist.</i>	<i>Value Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation’s impact.</i>
2	<i>The proposed facility shall provide open access to non-owner and non-employee oral surgeons and dentists.</i>	<i>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.</i>
3	<i>The facility shall provide only dental and oral surgical procedures requiring sedation.</i>	<i>Value Implementing this innovation through a demonstration project enables the State Health</i>

	CRITERION	BASIC PRINCIPLE AND RATIONALE
		<i>Coordinating Council to monitor and evaluate the innovation's impact.</i>
4	<i>The proposed facility shall obtain a license no later than one year from the effective date of the certificate of need.</i>	Access <i>Timely project completion increases access to services.</i>
5	<i>The proposed facility shall be certified by the Centers for Medicare and Medicaid Services (CMS), and shall commit to continued compliance with CMS conditions of participation.</i>	Access <i>Requiring service to indigent patients promotes equitable access to the services provided by the demonstration project facilities.</i>
6	<i>The proposed facility shall provide care to underserved dental patients. At least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients.</i>	Access <i>Requiring service to indigent patients promotes equitable access to the services provided by the demonstration project facilities.</i>
7	<i>The proposed facility shall obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or The Joint Commission (TJC), and shall commit to continued compliance with their respective standards.</i>	Safety and Quality <i>Adherence to certification processes ensures that the facility is committed to meeting the generally accepted industry standards for quality and safety for their patients.</i>
8	<i>Health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital by-laws, are required to establish or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency Department coverage responsibilities with at least one hospital.</i>	Safety and Quality <i>Encouraging health care professionals to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps ensure the continued viability of community-based resources for dental emergencies.</i>
9	<i>The proposed facility shall meet all reporting, monitoring and evaluation requirements of the demonstration project, set forth by the Agency.</i>	Safety and Quality, Access, Value <i>Timely monitoring enables the Agency to determine whether facilities are meeting criteria and to take corrective action if facilities fail to do so. This ensures that the demonstration project facilities meet all three Basic Principles.</i>
10	<i>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, 21 and older): (i) charity care; (ii) Medicaid; (iii) TRICARE; (iv) private insurance; (v) self-pay; and (vi) payment from other sources.</i>	Access <i>Requiring service to a wide range of patients promotes equitable access to the services provided by the demonstration project facilities.</i>
11	<i>The proposed facility shall demonstrate that it will perform at least 900 surgical cases per</i>	Value <i>Performing at least a minimum number of</i>

CRITERION	BASIC PRINCIPLE AND RATIONALE
<i>operating room during the third full federal fiscal year of operation. The performance standards in 10A NCAC 14C.2103 would not be applicable.</i>	<i>surgical procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.</i>

Timely reporting, monitoring and evaluation enables the Division of Health Service Regulation (Agency) to determine whether facilities are meeting criteria and to take corrective action if facilities fail to do so. To ensure that the demonstration project facilities meet all three Basic Principles, each selected site shall be required to provide annual reports to the Agency showing the facility's compliance with the criteria in Table 6D in the 2016 State Medical Facilities Plan. The Agency shall specify the report components and format. The Agency will produce an annual summary of each facility's annual report, and will evaluate the demonstration project after it has been in operation for three full federal fiscal years. Depending on the results as presented by the Agency, the State Health Coordinating Council shall consider whether to permit expansion beyond the original demonstration project sites."

Pursuant to the need determination, only one new Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms may be approved in this review for Region 3: HSAs V and VI, which includes Cumberland and Pitt counties. Furthermore, the proposal must be consistent with the requirements in Table 6D in the 2016 SMFP, which are identified above.

Additionally, there are two policies in the 2016 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3 states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

Policy GEN-4 states:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project, one to be located in Pitt County and the other to be located in Cumberland County, both of which are located within Region 3.

SCDP Greenville proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms to be located at 1720 West Arlington Blvd in Greenville (Pitt County).

Need Determination

SCDP Greenville's application is consistent with the need determination for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which includes Pitt County. Also, the application is consistent with the requirements in Table 6D in the 2016 SMFP, as follows:

1. The application contains a description of the percentage ownership interest in the facility by each oral surgeon and dentist. See Section II, pages 49-50, and Exhibit 4.
2. The applicants state that SCDP Greenville "*will provide open access to any credentialed dental professional, regardless of his or her ownership interest in the facility.*" See Section II, page 50.
3. The applicant states that only dental and oral surgical procedures that require anesthesia or sedation will be performed at SCDP Greenville. See Section II, page 51.

4. The applicant states that SCDP Greenville will be licensed as an ASC no later than one year from the effective date of the certificate of need. See Exhibit 11 and Section II, page 51, and Section II, page 59.
5. In Exhibit 11, Section II, page 51 and Section II page 59, the applicant commits to having SCDP Greenville certified by the Centers for Medicare and Medicaid Services (CMS) and further commits to continued compliance with the CMS conditions of participation.
6. In Section IV, pages 138-142 and Section VI.14, pages 167-170, the applicant demonstrates that it will provide care to underserved dental patients and that *“at least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients.”*
7. SCDP Greenville will obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or The Joint Commission (TJC), and shall commit to continued compliance with their respective standards. See Section II.7, page 59 and Exhibit 11.
8. The applicant states in Exhibit 11 and Section II, page 52, that health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital by-laws, will be required to establish or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency Department coverage responsibilities with at least one hospital.
9. The applicant states the facility will provide all reporting, monitoring and evaluation requirements of the demonstration project criteria. See Exhibit 11 and Section II, page 53.
10. The applicant provided the projected number of patients for the following payor types, broken down by age (under 21, 21 and older): (i) charity care; (ii) Medicaid; (iii) TRICARE; (iv) private insurance; (v) self-pay; and (vi) payment from other sources for each of the first three full federal fiscal years of operation. See Section IV, pages 138-139.
11. In Section III.b, pages 104-117, and Section IV, page 136, the applicant demonstrates that it will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation.

Policies

Policy GEN-3

SCDP Greenville addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.6, pages 57-59, Section II.8, pages 59-61, Section III.4, pages 120-121 and Exhibit 14. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, pages 121-124. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, page 124, Section X, pages 189-191 and the applicant's pro forma financial statements, pages 201-207. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Policy GEN-4

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section III.4, pages 124-125 and in Section XI.8, page 197, the applicant describes its plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency. However, the applicant does not describe the project's plan to assure water conservation. Therefore, the application is not consistent with Policy GEN-4.

In summary, the application is consistent with the need determination in the 2016 SMFP and Policy GEN-3. However, the application is not consistent with Policy GEN-4. Consequently, the application is not conforming to this criterion.

Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms to be located at 2038 Litho Place in Fayetteville (Cumberland County).

Need Determination

Valleygate's application is consistent with the need determination for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which includes Cumberland County. Also, the application is consistent with the requirements in Table 6D in the 2016 SMFP, as follows:

1. The application contains a description of the percentage ownership interest in the facility by each oral surgeon and dentist. See Section I.12, page 18.
2. The applicants state that Valleygate “*will provide open access to any credentialed dental professional, regardless of his or her ownership interest in the facility.*” See Section III.4, page 110 and Exhibits 8 and 9.
3. The applicants state that only dental and oral surgical procedures that require anesthesia or sedation will be performed at Valleygate. See Section II.1, pages 30-37 and Section III.4, page 110.
4. The applicants state that Valleygate will be licensed as an ASC no later than one year from the effective date of the certificate of need. See Section III.4, page 110 and Section XII, page 221.
5. In Exhibit 12, Section III.4, page 111 and Section XII, page 221 the applicants commit to having Valleygate certified by the Centers for Medicare and Medicaid Services (CMS) and further commits to continued compliance with the CMS conditions of participation.
6. In Section III.4, page 111 and Section VI.14, pages 176-180, the applicants demonstrate that they will provide care to underserved dental patients and that at least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients. See also Exhibit 30.
7. Valleygate states it will obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or The Joint Commission (TJC), and shall commit to continued compliance with their respective standards. See Exhibit 12, Section III.4, page 111 and Section XII, page 221
8. The applicants state in Section I.13(d), page 24, Section III.4, page 112 and Section V, pages 149-151 and 154-155 that health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital by-laws, will be required to establish or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency Department coverage responsibilities with at least one hospital.
9. The applicants state that the facility will provide all reporting, monitoring and evaluation requirements of the demonstration project criteria. See Section III.4, page 112.

10. In Section III.4, page 113, the applicants provide the payor mix projections by age and payor type only for Year 2 (FFY2019), and not for the first three full federal fiscal years. Also, the applicant's payor mix projections show "*SelfPay/Indigent*" as one category, and "*Commercial Insurance*," "*Medicare/Medicare Managed Care*," "*Medicaid*," "*Managed Care*" and "*Military*" as the other payor categories, rather than the payor categories described in this criterion. The Agency determined there was enough information provided in the application as submitted to calculate payor mix projections for Year 3 (FFY2020), but not Year 1 (FFY2018). Nevertheless, the need determination in the 2016 SMFP does not specify any standard or requirement with regard to the payor mix percentages other than those discussed above in Criterion #6 in Table 6D in the 2016 SMFP. As such, the applicants can be and are conditioned to provide the payor mix percentages for Year 1 that were omitted from the application.
11. In Section III.4, page 113 and in Section IV, pages 132-146, the applicants project that they will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation.

Policies

Policy GEN-3

Valleygate addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.6, page 41, Section II.8, pages 43-44, Section III, page 116 and Exhibit 16. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, page 115. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, pages 114-115, Section X, pages 206-210, Exhibit 40, and the applicant's pro forma financial statements, pages 223-249. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Policy GEN-4

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section III.4, pages 116-117 and in Section XI.8, page 218, the applicants describes their plan to assure improved energy efficiency and water conservation. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is consistent with Policy GEN-3, Policy GEN-4 and with the need determination in the 2016 SMFP. Consequently, the application is conforming to this criterion.

Conclusion

In summary, both applicants adequately demonstrate that their proposal is consistent with the need determination in the 2016 SMFP for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which includes both Pitt and Cumberland counties. However, the limit on the number of Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects with up to two operating rooms to be located in Region 3: HSAs V and VI that may be approved in this review is one project. Collectively, the two applicants propose a total of two Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects. Therefore, even if both applications were conforming to all statutory and regulatory review criteria, both applications cannot be approved.

SCDP Greenville's application is conforming to the need determination and Policy GEN-3. However, SCDP Greenville's application is not conforming to Policy GEN-4, and thus, is not conforming to this criterion. Valleygate's application is conforming with the need determination, Policy GEN-3 and Policy GEN-4. Therefore, Valleygate's application is conforming to this criterion. See the Summary following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C- Both Applications

On page 90, the 2016 SMFP states,

“The Project establishes a special need determination for up to four new separately licensed dental single specialty ambulatory surgical facilities with up to two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the four following regions:

- *Region 1: HSA IV*
- *Region 2: HSA III*
- *Region 3: HSA V and HSA VI*
- *Region 4: HSA I and HSA II*

As stated above, the 2016 SMFP defines the Region 3 service area as HSAs V and VI, which includes Anson, Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Edgecombe, Gates, Greene, Halifax, Harnett, Hertford, Hoke, Hyde, Jones, Lenoir, Martin, Montgomery, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Richmond, Robeson, Sampson, Scotland, Tyrell, Washington, Wayne and Wilson counties. Providers may serve residents of counties not included in their service area.

SCDP Greenville proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space in an existing building at 1720 West Arlington Blvd in Greenville (Pitt County). In Section I.10, pages 6-7, the applicant states SCDP Greenville will lease the space from Pico Properties, LLC, and management of the facility will be contracted to Papillon Management, LLC. SCDP Greenville is a limited liability company whose sole member is Surgical Center for Dental Professionals of NC, LLC (SCDP of NC, LLC). In Section I.12, page 8, the applicant states

“Surgical Center for Dental Professionals of NC, LLC (SCDP of NC, LLC) is a joint venture entity to be comprised of dental professionals, anesthesiologists and other clinical and non-clinical investors. At the time of submission of this application, 22.65 percent of the available shares have been committed. Dr. Uday Reebye currently holds 18 percent ownership of the LLC. An additional three percent is currently owned by a number of dentists and other dental professionals. An additional 1.65 percent is currently owned by non-clinical investors.”

In Section II.1, pages 48-49, the applicant describes the proposed project as follows:

“SCDP of Greenville proposes to lease 9,868 square feet of space, primarily on the first floor in an existing building located at 1720 West Arlington Boulevard in Greenville for the development of the proposed dental ASC. The ASC will house two licensed operating rooms, two procedure rooms, an anesthesia workroom and control room, a sterilization room, an X-ray room, dry and wet lab area, and clean and soiled utility and supply, as well as men’s and women’s locker facilities, all within the sterile corridor shaded blue on the proposed line drawings (Exhibit 10). ... A nurse station, triage area, and pre-operative and post-operative spaces, which are accessible via the sterile corridor, will support the two operating rooms and two procedure rooms, and are shaded orange on the proposed line drawing (Exhibit 10). Additional spaces for a staff lounge, electrical room, and medical

gases are also shaded orange. ... Non-clinical support spaces including receiving and registration, general and pediatric patient waiting, medical records, and toilets are shaded yellow on the proposed line drawings (Exhibit 10). Administrative and storage spaces, including offices, a conference/training room, and open work area will be identified on the proposed line drawings (Exhibit 10)."

Population to be Served

In Section III.6, pages 126-127, the applicant provides the projected patient origin for the proposed facility during the first two operating years (OY) (FFY2018-2019), as summarized in the table below:

**SCDP Greenville
Projected Patient Origin**

County (HSA)	OY 1 Projected Patients FFY2018	OY 2 Projected Patients FFY2019	Projected Percent of Total Patients
Pitt (VI)	896	1008	37.2%
Wilson (VI)	281	316	11.6%
Nash (VI)	199	224	8.3%
Harnett (V)	193	217	8.0%
Wayne (VI)	131	148	5.4%
Duplin (VI)	129	145	5.4%
Greene (VI)	115	130	4.8%
Halifax (VI)	81	91	3.4%
Cumberland (V)	77	87	3.2%
Lenoir (VI)	62	70	2.6%
New Hanover (V)	58	66	2.4%
Johnston (IV)	55	61	2.3%
Onslow (VI)	48	54	2.0%
Edgecombe (VI)	38	42	1.6%
Craven (VI)	10	11	0.4%
Northampton (VI)	5	6	0.2%
Sampson (V)	3	3	0.1%
Beaufort (VI)	2	3	0.1%
Bertie (VI)	1	1	0.0%
Martin (VI)	1	1	0.0%
Hertford (VI)	1	1	0.0%
Jones (VI)	1	1	0.0%
Robeson (V)	1	1	0.0%
Washington (VI)	1	1	0.0%
Other*	24	27	1.0%
Total	2,413	2,714	100.0%

*Other includes Franklin, Granville, Randolph, Warren and Wake counties and other states.

In Section III, pages 127-128, with regard to its assumptions and methodology for projected patient origin, the applicant states,

“For the users or referrers that could provide internal data, SDCP of Greenville analyzed patient origin mix and applied that mix to the projected cases for that user or referrer. For users that could not provide internal data to SDCP of

Greenville for analysis, SCDP of Greenville assumed their patients would originate from the county where their practice is currently located. Thus, for example, the cases to be performed by a user with an office in Pitt County were all assumed to originate from Pitt County. SCDP of Greenville then applied each user or referrer's patient origin mix to its expected number of cases and summed the results. The resulting patient origin reflected in the above table is, thus, based on the users and referrers involved in the proposed project. In particular, please note that due to projected contribution of cases from Triangle Implant Center-Wilson, the patient origin of SCDP of Greenville reflects the patient origin of Triangle Implant Center-Wilson including cases from Wilson County and its adjacent counties. SCDP of Greenville believes these projections are conservative in terms of the number of counties from which patients are likely to originate; however, it chose to project patient origin based solely on available data from users and referrers rather than estimate using a less reliable methodology."

The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III, pages 68-104, of the application and referenced exhibits, the applicant describes the factors which it states support the need for the proposed project, including:

- Need identified in the 2016 SMFP (pages 70-72);
- Unmet need for facilities to accommodate dental procedures with sedation or anesthesia (pages 72-82);
- Population growth in the service area (Region 3) (pages 82-87);
- Need for Dental Education and Shortage of Dentists (pages 87-91); and
- Improve access, quality, value, collaboration and coordination (pages 91-104)

The information provided by the applicant on the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section IV.1, page 136, the applicant provides the projected utilization for the operating rooms and procedure rooms at its proposed facility for the first three OYs (FFY2018 – 2020) following completion of the project, which is summarized below:

SCDP Greenville

	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Dental Outpatient ORs			
# of ORs	2	2	2
Total OR Cases	1,600	1,800	2,000
Average OR Cases per OR	800	900	1,000
Dental Procedure Rooms			
# of Procedure Rooms	2	2	2
Total # of Procedures	813	914	1,016
Average Per Procedure Room	407	457	508

Regarding the demonstration project in the 2016 SMFP, Criterion #11 in Table 6D, page 91, states: *“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.2103 would not be applicable.”* As shown in the table above, SCDP Greenville projects 1,000 OR cases per OR in the third full federal fiscal year of operation (OY3).

In Section III.b, pages 104-117, the applicant provides the assumptions and methodology used to project utilization for the proposed SCDP Greenville facility, summarized as follows:

- Estimated use rates for dental and oral surgical cases per 1,000 population per county based on historical data from several of its Triangle Implant Centers (pages 104-107).
- Calculated potential need in Region 3 utilizing current and projected population data and use rates per 1,000 derived from the historical data of its Triangle Implant Centers (pages 107-108).
- Calculated use rates per 1,000 of population for outpatient oral surgery cases in hospitals and ASCs for both North Carolina and Region 3 and derived potential need (pages 108-111).
- Calculated projected utilization based on support letters of projected users of SCDP Greenville (pages 111-112 and Exhibit 29).
- Added in historical cases currently performed at Triangle Implant Center-Wilson which are expected to shift to SCDP Greenville (pages 112-113).

Projected utilization is based on reasonable and adequately supported assumptions.

Based on review of: 1) the information provided by the applicant in Section III, pages 68-104, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicant’s response to the comments received at the public hearing, the applicant adequately documents the need to develop the proposed dental single specialty ambulatory surgical facility in Region 3.

Access

Regarding the demonstration project in the 2016 SMFP, Criterion #6 in Table D, pages 90-91, states:

“The proposed facility shall provide care to underserved dental patients. At least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients.

In Section IV, pages 136-142 and in Section VI.14, pages 167-170, the applicant projects that 4.2% of total patients will receive charity care and 63.9% will be Medicaid recipients. Furthermore, on page 154, the applicant states *“The development of the proposed project will allow SCDP of Greenville to provide services to all persons in need of dental surgical care requiring sedation, regardless of financial status, race, ethnicity, sex, disability, age or source of payment.”* Exhibit 23 contains a copy of the applicant’s *“Admission Policies and Patient Selection Criteria”* See also Section VI, pages 154-159. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space in a new building to be located at 2038 Litho Place in Fayetteville (Cumberland County).

In Section I.10, page 15, the applicants state Valleygate will lease the space from VFD Real Estate Partners, LLC, and that management of the facility will be contracted to Knowles, Smith and Associates, LLP. In Section I.12, page 18 the applicants state Valleygate is a limited liability company whose members are seven dentists, each of whom holds a 14.3 percent ownership interest. The applicants state that each of the dentists is also an owner of Knowles, Smith and Associates. In Section II.1, page 30, the applicants describe the proposed project as follows:

“It will have two operating rooms, two special procedure rooms, and a ten-unit pre- and post-surgery care area, which will include four private rooms available for exams and minor dental treatments. The applicants will have the entire facility designed specifically for dental and oral surgery cases; and, its design will accommodate a flexible response to changing care delivery patterns. The four private rooms in the pre- and post-surgery area will have flexibility for use for history or physical examinations prior to admission, as well as for procedures that require

conscious sedation, but do not require the full design support of a special procedure room or an operating room.”

In addition to the two operating rooms, the applicants propose to develop two procedure rooms and one treatment room (“*dental treatment suites, also called dental operatories*”). On page 32, the applicants describe the two procedure rooms as follows:

“These procedure rooms will meet the same construction and life safety standards as the two operating rooms, making it available for surgical cases that require general anesthesia. Either an Anesthesiologist or a CRNA will staff all cases completed in the procedure rooms. The rooms will have the same sterile environment and be located with the operating rooms in the sterile core area ‘behind the yellow line.’ The procedure rooms will accommodate dental cases ranging from extractions and restorations under conscious sedation, to complex cases under general anesthesia.”

On page 33, the applicants describe the treatment rooms as follows:

“Outside the operating room sterile core, will be dental treatment suites and recovery rooms. The applicant will equip the dental treatment suites, also called ‘dental operatories,’ with the same equipment used in the current Village Family Dental offices. Design of these rooms will accommodate a variety of dental procedures for both adults and children. These rooms will be distinct from the operating rooms as they will not be equipped for general anesthesia, but will support sedation. Only dentists licensed to provide sedation by the NC Dental Board will provide dental treatment under IV or oral sedation in these rooms. The 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....

The applicants state that typical procedures to be performed in the treatment rooms will include tooth extractions, endodontic therapy (root canals), and dental crowns. On page 33, the applicants state,

“When not in use for procedures, the treatment rooms will also be used for pre-procedure anesthesia interviews, where the surgery center’s staff anesthesiologist will perform a history and physical (H & P) and discuss anesthesia options with the patient and family (‘anesthesia interview’). ... Finally, during the peak load part of the day, when pre- and post-procedure patients overlap, these rooms will support overflow pre- and post-procedure care.”

Population to be Served

In Section III.6, pages 119-121, the applicants provide the projected patient origin for the proposed facility for the first two operating years (FFY2018-2019), as summarized in the table below.

**Valleygate
Projected Patient Origin**

County (HSA)	Projected Percent of Total Patients
Cumberland (V)	30.0%
Robeson (V)	20.0%
Harnett (V)	9.0%
Sampson (V)	6.8%
Duplin (VI)	5.8%
Columbus (V)	5.3%
Moore (V)	5.2%
Richmond (V)	4.7%
Hoke (V)	4.4%
Scotland (V)	4.0%
Bladen (V)	2.9%
Other*	2.0%
Total	100.0%

* The applicants state on page 120 that, historically, approximately 2.0% of KSA patients come from outside the identified 11-County service area and therefore “Other” is projected at 2.0%.

The applicants provide the assumptions and methodology used to project patient origin for the proposed project on pages 119-121. The applicants state:

“The applicants used the following information to project patient origin:

- *The current patient origin for the seven dental practices of Knowles, Smith and Associates;*
- *The practice locations of the non-KSA dentists that have committed to using the facility;*
- *Expected referrals to the licensed, independent practitioners of the facility from community health centers; and*
- *Need in the 11 county service area identified above.”*

See also the assumptions and table on pages 120-121 of the application.

The applicants adequately identify the population to be served.

Analysis of Need

In Section III, pages 51-89, and referenced exhibits, the applicants describe the factors which they state support the need for the proposed project, including:

- Need identified in the 2016 SMFP (pages 52-54).
- Unmet need of pediatric patients in the service area (pages 51-52; 54-64).

- Treatment Guidelines for Special Needs Children and Adults (pages 65-66).
- Barriers to Dental Treatment (pages 68-72).
- Need to improve access including military (pages 80-89).

The information provided by the applicants on the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section IV.1, page 132, the applicants provide projected utilization for the proposed Valleygate facility during the first three OYs (FFY2018 – 2020), as illustrated in the table below:

Valleygate			
	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Dental Outpatient ORs			
# of ORs	2	2	2
Total OR Cases	1,613	1,879	1,930
Average OR cases per OR	806	939	965
Dental Procedure Rooms			
# of Procedure Rooms	2	2	2
Total # of Procedures	1,243	1,662	1,932
Average Per Procedure Rooms	622	831	966
Dental Treatment Rooms			
# of Treatment Rooms	1	1	1
Total Treatment Cases	217	269	293
Overall Total	3,073	3,809	4,156

Regarding the demonstration project in the 2016 SMFP, Criterion #11 in Table 6D, page 91, states: *“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.2103 would not be applicable.”* As shown in the table above, Valleygate projects to perform an average of 965 cases in each OR in the third full federal fiscal year of operation (OY3).

In Section III, pages 91-104, and Section IV, pages 133-145, the applicants provide the assumptions and methodology used to project utilization of the proposed facility, summarized as follows:

The applicants first projected the total number of dental surgeries under anesthesia (all facilities) in the 11 counties that represent the applicants’ primary market. The central assumption is that the majority of patients who truly need dental surgeries in operating rooms are children under the age of nine, some children over the age of nine and some adults who also need dental surgery and oral surgery in a licensed operating room. (See page 90). The

methodology and assumptions used to project the number of dental surgeries is set forth in nine steps on pages 91-104 of the application.

Step 1: Determine the percent of KSA Medicaid beneficiaries under age nine years of age who required dental procedures under anesthesia (See page 91)

Knowles, Smith & Associates, LLP (KSA) is a large dental practice already currently serving patients in the proposed market. The applicants looked at the history of KSA Medicaid beneficiaries under the age of nine who had a dental procedure in a hospital operating room for the years 2012, 2013 and 2014. See Table III.6 on page 91. Assumptions utilized were:

- *“Children under age 9 are the largest population treated by KSA in operating rooms and are the largest age group in need.*
- *KSA’s large Medicaid population of Medicaid children, provides a reasonable estimate of need in this demographic group.*
- *Need for dental care under general anesthesia is similar among Medicaid children [sic] does with the state.”*

Step 2: Estimate percentage of Medicaid beneficiaries under age nine who are seen for dental services of any kind and require dental procedures under anesthesia. (See page 92)

The applicants estimate that 36.3 percent of Medicaid patients under age nine who are seen for treatment would need care in operating rooms based on KSA data from 2012. The rationale for utilizing the 36.3 percent is set forth on page 92 of the application.

Step 3: Determine the Population Growth Rate for Children Under age nine in Health Service Area (HSA) V and VI from 2014 to 2020 (See page 93)

In Table III.7, on page 93, the applicants provide the projected population of children under the age of nine from 2014-2020 for all six HSAs and determine the compound annual growth rate (CAGR). Population data was obtained from the North Carolina Office of State Budget and Management (OSBM).

Step 4: Project Medicaid Beneficiaries Under Age Nine who will Have a Dental Treatment EPSDT Service for [sic] 2014 to 2020 (See page 94)

On page 77, the applicants state *“In North Carolina, Medicaid-eligible children under the age of 21 have rights to all medical necessary health care services under the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program. Section 1905(a) of the Social Security Act describes these ‘necessary’ services. EPSDT benefits include dental services.”*

The applicants obtained the actual number of patients under age nine who had a dental treatment in 2014 for each of the six HSAs in the state and then, using the CAGR derived in Step 3, calculated projected Medicaid Beneficiaries Under Age Nine Receiving Any Dental

Treatment for the years 2015-2020 for each HSA. See Table III.8, page 94. Additional assumptions used:

- *“Medicaid beneficiaries will increase in direct proportion to population increases.*
- *Proportion of Medicaid children treated will remain constant. Increases will occur only as population increases. This is a very conservative assumption. Increased access may, in fact increase the proportion of eligible Medicaid beneficiaries who receive dental treatment.”*

Step 5: Estimate number of Medicaid beneficiaries under age nine who will require dental procedures under general anesthesia (See page 95)

Table III.9, page 95, shows the estimated number of Medicaid beneficiaries under age nine who will require dental procedures under general anesthesia. The applicants multiplied the projected number of Medicaid patients expected to have a dental treatment (See Table III.8) times the expected number of Medicaid patients under the age of nine who will require dental treatment under anesthesia as determined in Step 1. See assumptions on page 95.

Step 6: Determine Percentage of Dental Operating Room Cases Served that are not Medicaid Beneficiaries Under Nine Years of Age (See page 96)

Step 7: Project Need for Dental Cases Under General Anesthesia for all Patients in all HSAs for 2015-2016 (See page 97)

In Table III.11, page 97, the applicants project the number of operating room cases under general anesthesia by HSA for individuals under age nine using the results of Step 5 multiplied by 1.4924 (the ratio of estimated non-Medicaid to Medicaid cases from Step 6).

Step 8: Determine Percent Dental Surgery Cases in Operating Rooms for Individuals Aged Nine or Over (See pages 98-104)

On page 98, the applicants concluded that 8.82% of the dental surgery cases in hospitals or ASCs was for individuals aged 21 or over. The methodology, assumptions and calculations are set forth on page 98 of the application.

Step 9: Estimate the Total Need for Children and Adults (See pages 99-104)

In Table III.13, page 99, the applicants estimate the total number of persons in need of dental surgery utilizing general anesthesia by year and HSA. The methodology, assumptions and calculations are set forth on pages 99-104 of the application. The applicants estimate 17,210 individuals will be in need of dental surgery under general anesthesia in 2018 in HSAs V and VI (Region 3).

In Section IV, pages 133- 145, the applicants provide the assumptions and methodology used to project utilization of the proposed facility, summarized below:

In Part 1, the applicants first describe the methodology and assumptions utilized to project utilization for the entire facility.

Entire Facility

Step 1: Estimate the Percentage of Need Served in First Three Years (pages 133-136)

Step 2: Estimate the 2018-2020 Total Projected Referrals (page 137)

In Table IV.5 page 137, the applicants project the estimated Valleygate cases by year as shown below:

Notes	Metric	FFY 2018	FFY 2019	FFY 2020
a	Need for Dental Surgery Cases in Hospitals and ASCs in the Proposed Service Area	7,681	7,618	7,556
b	Estimated Valleygate Percent of Need Served	40.0%	50.0%	55.0%
c	Projected Cases Served By Valleygate	3,073	3,809	4,156

Notes: “a”: From Table III.6, page 104, of the application;
“b”- Assumptions from Step 1:
“c”- (a * b)

In Section IV.1, page 134, the applicants estimate that referral sources who have expressed an interest and support for the project would refer 3,230 dental surgical cases to the proposed dental ASF, annually, based on “*letters, person-to-person meetings, phone calls and emails.*” On pages 133-134, the applicant states that all of the pediatric dentists in the 11 county service area have indicated an interest in bringing cases to the proposed facility. In Table IV.2, page 134, the applicants provide a list of estimated historical OR volumes from these referral sources.

As illustrated in the table above, the applicants forecast that in OY1 (FFY2018), Valleygate will initially serve 40% of the projected total number of cases in the 11 county market, which is expected to increase to 50.0% in OY2 (FFY2019) and 55.0% in OY3 (FFY2019). The assumptions supporting these projections are described on pages 135-136.

Service Components: Treatment Rooms, Procedure Rooms and ORs

In Part 2, the applicants describe how projected utilization for each service component is derived.

Treatment Rooms

Step 3 [sic]: Determine Percent Procedures for Persons Over Age 21 (page 137)

Based on 2015 data from the North Carolina Division of Medical Assistance, the applicants state that 8.82% of the dental surgery cases in hospitals or ASCs were performed on patients 21 years or older.

Step 4 [sic]: Determine Percent Procedures to be Done in the Dental Treatment Rooms (page 138)

On page 138, the applicants state,

“General anesthesia is often clinically indicated for special needs adults. Recognizing that most of the literature indicates that general anesthesia for adults is rarely necessary; the applicant assumes that 80 percent of the adults (persons over 21) appropriate for treatment the facility will not require general anesthesia, hence will use the dental treatment rooms.

*Assuming that only this group uses the dental treatment rooms, the applicant assumes that 7.05 percent of total cases will use the dental treatment rooms (8.2% [sic] adult cases * 80% in treatment rooms = 7.05% of total cases). The remaining adults, the special needs groups, will use the operating rooms or procedure rooms.”*

To determine the total cases in treatment rooms for the first three operating years, the applicants multiplied the total cases from Table IV.5 x 7.05%, as illustrated below.

Table IV.7 – Total Cases in Treatment Rooms

FFY 2018	FFY 2019	FFY 2020
217	269	293

ORs and Procedure Rooms

On pages 138-146, in Steps 3-10, which are briefly described below, the applicants describe the methodology and assumptions used to distribute the remaining cases between the ORs and the procedure rooms.

Step 3: Determine the Distribution of Procedures in the Operating and Procedure Rooms (pages 138-139)

Step 4: Calculate the Number of Operating Room Cases (page 140);

Step 5: Calculate the Number of Operating Rooms Needed for High Acuity Cases (page 141);

Step 6: Determine the Remaining Number of General Anesthesia Cases (page 142)

Step 7: Distribute Remaining Cases between Operating and Procedure Rooms (pages 143-144)

Step 8: Summarize Cases by Room Type (pages 144-145)

Step 9: Calculate Treatment Rooms Use for Histories and Physicals (page 145)

Step 10: Calculate Spaces Needed for Preparation and Recovery Function (page 146)

Based on the applicants' assumptions regarding patient acuity levels, surgical case times, and room capacity, the applicants project the distribution of cases among the three room types for the first three operating years in a table on page 144, which is summarized below:

Projected Cases by Room Type	Number of Rooms	FFY 2018	FFY 2019	FFY 2020
Operating Rooms	2	1,613	1,878	1,930
Procedure Room	2	1,243	1,662	1,932
Treatment Rooms	1	217	269	293
Total Cases		3,073	3,809	4,156

Source: Table on page 144 of the application.

As discussed above, the projected surgical cases to be performed at the proposed dental ASF are based on the applicants' historical experience regarding the percentage of patients that will require a dental procedure under general anesthesia, the total projected number of Medicaid patients under age 9 who will require dental services in the proposed market based on DMA estimates and projected population growth in the proposed market. Estimates of dental surgery cases in operating rooms for patients over the age of 9 is based on data provided by the DMA. The market share projections are supported by letters in Exhibits 26 and 33 from dental professionals and other healthcare providers in the proposed market who have expressed support for the proposed project and their intention to refer patients to the proposed facility.

Projected utilization is based on reasonable and adequately supported assumptions.

Based on review of: 1) the information provided by the applicants in Section III, pages 51-89, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicants' response to the comments received at the public hearing, the applicants adequately document the need to develop the proposed dental single specialty ambulatory surgical facility in Region 3.

Access

Regarding the demonstration project in the 2016 SMFP, Criterion #6 in Table 6D, pages 90-91, states:

“The proposed facility shall provide care to underserved dental patients. At least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients.

In Section VI.14, pages 176-180, the applicants project 5.3% of total patients will receive charity care and 88.5% will be Medicaid recipients. Furthermore, on page 163, the applicants state they are *“fully committed to providing service to all persons, regardless of gender, race, ethnicity, income or age.”* Exhibit 38 contains a copy of the applicants’ *“Non-discrimination”* policy. See also Section VI, pages 163-167 and Exhibit 30 (Charity Care Policy). The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C- Both Applications

SCDP Greenville. In Section III.8, pages 128-132, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

1. Maintain the status quo – The applicant considered maintaining the status quo, however this alternative would not have met the unmet need for dental procedures with sedation, including not enhancing quality, access and value and maintaining the status quo would also not have permitted the fostering of collaboration and coordination of care. In addition, the setting provided by the proposed SCDP Greenville facility permits additional reimbursement in the form of a facility fee which allows SCDP Greenville to extend subsidized care.

2. Develop project in a different location – The applicant considered developing the proposed SCDP Greenville facility in a different location within Region 3; however, Pitt County is centrally located within Region 3 combined with the fact that Greenville is the largest centrally located municipality within Region 3 thus the proposed location provided the best access to the residents of Region 3. Therefore, this was not an effective alternative.
3. Develop a pediatric-only ASC – The applicant considered developing a pediatric-only ASC however this was rejected as it would not promote equitable access to dental services requiring sedation or anesthesia. Therefore, the applicant determined that this was not an effective alternative.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming or could be conditioned to be conforming to all other applicable statutory and regulatory review criteria. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming even though it is not consistent with Policy GEN-4 as that inconsistency could be corrected by a condition requiring a statement about plans for water conservation.

Valleygate. In Section III.8, pages 122-125, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

1. Maintain the status quo – The applicants considered maintaining the status quo, however this alternative would not resolve the current lack of access to ORs in local hospitals and freestanding ASCs combined with the lack of dental specific equipment in the multi-specialty ORs which hinders dentists’ ability to effectively treat dental disease in the market. Therefore, this was not an effective alternative.
2. Complete procedures under general anesthesia in dental offices – The applicants considered completing procedures under general anesthesia in dental offices; however, many patients require general anesthesia and for those patients who are appropriate for outpatient care, a licensed surgical facility is the safest location. The applicants state that a dental office is not staffed, equipped or supplied to provide the maximum safety for a patient who is incapacitated by general anesthesia.
3. Locate the facility in a different location – The applicants considered developing the proposed Valleygate facility in another location but state that the current proposed location is ideal as it is the closest to *“the highest concentration of need in the region and the communities where existing facilities provide no, or limited, access to licensed surgical rooms. ... the chosen site is organized as a center for dental referrals, and is adjacent to other supporting services and to specialists who can*

consult on particularly complex cases.” Therefore, the applicants determined that this was not an effective alternative.

4. Select different scope of service, focus less attention on pediatrics- The applicants considered selecting a different scope of service with less focus on pediatrics, however, the applicants determined that there was extensive need among children under the age of nine with a small percentage of adults who will be candidates for surgery at the proposed Valleygate facility. The applicants, based on extensive research and institutional knowledge, estimate that 93 percent of the cases at the proposed Valleygate facility will be children with the majority under the age of nine. Further, the applicants expect there to be limited need for adult oral surgery in a licensed surgical facility both because of low demand and due to the fact that oral surgeons can obtain hospital admitting privileges and thus do not face the same obstacles that general and pediatric dentists face in accessing block time in an OR. Therefore, the applicants determined that this was not an effective alternative.

After considering those alternatives, the applicants state the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

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

C- Both Applications

SCDP Greenville proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space in an existing building at 1720 West Arlington Blvd in Greenville (Pitt County).

Capital and Working Capital Costs

In Section VIII., pages 182-183, the applicant states that the total capital cost is projected to be as follows:

Construction	\$2,428,088
Fixed Equipment	\$560,161
Movable Equipment	\$57,000
Furniture	\$114,000
Architect & Engineering fees	\$238,000
Financing Costs	\$25,000
Interest during Construction	\$250,000
Total	\$3,672,249

In Section IX, page 188, the applicant states that there will be \$138,457 in start-up costs and \$450,650 in initial operating expenses, for total working capital required of \$589,106.

Availability of Funds

In Section VIII.3, page 183, the applicant states that the capital cost of the project will be financed with a conventional loan. In Section IX.2, page 188, the applicant states that the working capital costs for the project will also be financed with a commercial loan. Exhibit 25 contains a letter dated April 12, 2016 from the Vice President of PNC Bank, National Association, documenting its intention to provide funding in the amount of \$4,800,000 for the proposed project which covers both the capital and the working capital costs which total \$4,261,355 (\$3,672,249 + \$589,106 = \$4,261,355). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Forms B/C), the applicant projects that revenues will exceed operating expenses in both the second and third operating years following completion of the proposed project, as shown in the table below.

	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Total Gross Revenue	\$4,729,118	\$5,319,033	\$5,910,908
Total Net Revenue	\$2,922,311	\$3,286,914	\$3,652,615
Net Revenue Per Case	\$1,211	\$1,211	\$1,211
Total Operating Expenses	\$2,941,653	\$2,963,955	\$2,981,050
Net Income (Loss)	(\$19,342)	\$322,959	\$671,565

However, in Form B/C, page 202, the applicants include a line item under Indirect Expenses labeled “Professional Fees” in the amounts of \$498,000, \$507,960 and \$518,119 respectively for the first three operating years. In the Form B/C Assumptions on pages 203-204, the applicant states both 1) “SCDP of Greenville will not bill or collect professional fees, which will be billed separately by each user.” and 2) “Professional fees expense includes fees for anesthesiologists and other professional fees, based on the experience of SCDP of Greenville’s management company and discussions with Regional Anesthesia, inflated 2% per year.” See footnotes 2 and 17 on pages 203-204. Thus SCDP provides conflicting

information regarding professional fees. If “Professional Fees” are not included in Total Operating Expenses, Net Income increases each year, as shown in the following table.

	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Total Gross Revenue	\$4,729,118	\$5,319,033	\$5,910,908
Total Net Revenue	\$2,922,311	\$3,286,914	\$3,652,615
Total Operating Expenses	\$2,941,653	\$2,963,955	\$2,981,050
“Professional Fees”	\$498,000	\$507,960	\$518,119
Total Operating Expenses less “Professional Fees”	\$2,443,653	\$2,455,995	\$2,462,931
Net Income (Total Net Revenue – Adjusted Total Operating Expenses)	\$478,658	\$830,919	\$1,189,684

Either way, the applicant projects a profit in OYs 2 and 3.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges (with the exception of conflicting statements regarding professional fees). See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space a new building to be located at 2038 Litho Place in Fayetteville (Cumberland County).

Capital and Working Capital Costs

In Section VIII, pages 195-198, the applicants state the total capital cost is projected to be as follows:

VFD Real Estate Partners, LLC (Lessor)	
Site Costs	\$ 450,000
Construction	\$2,836,852
Architect/Engineering Fees	\$ 200,000
Interest During Construction	\$ 34,561
Additional Contingency (10%)	<u>\$ 352,141</u>

Total \$3,873,554

Valleygate Dental Surgery Center of Fayetteville, LLC (Lessee and Operating Entity)

Fixed Equipment Purchase/Lease	\$633,099
Movable Equipment Purchase/Lease	\$115,883
Furniture	\$ 57,693
Consultant Fees	\$ 73,000
Additional Contingency (10%)	<u>\$ 87,967</u>
Total	\$967,642

The total combined capital cost is \$4,841,196 ($\$3,873,554 + \$967,642 = \$4,841,196$).

In Section IX.1, page 204, the applicants state there will be \$60,792 in start-up costs and \$727,575 in initial operating expenses, for total working capital required of \$788,366.

Availability of Funds

In Section VIII.3, page 199, the applicants state that both VFD Real Estate Partners, LLC and Valleygate Dental Surgery Center of Fayetteville, LLC portions of the capital cost of the proposed project will be financed by a conventional loan. In Section IX, page 205, the applicants state that the working capital costs of the proposed project will be financed by a line of credit.

In Exhibit 42, the applicants provide a letter dated April 13, 2016 from Eddie Bray, Senior Vice President of First Citizens Bank which states First Citizens Bank is committed to provide financing to VFD Real Estate Partners, LLC in the amount of \$4,000,000, to build the proposed new dental ASC in Fayetteville.

However, the application does not adequately document availability of funds for the stated capital and working capital needs of Valleygate Dental Surgery Center of Fayetteville, LLC (Lessee and Operating Entity).

Therefore, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project subject to Condition #6, which can be found at the end of this document.

Financial Feasibility

For the entire facility, in the projected revenue and expense statement, Form B, the applicants project revenues will exceed operating expenses in both the second and third operating years following completion of the proposed project, as shown in the table below.

Valleygate Dental Surgery Center of Fayetteville- Entire Facility

	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Total Gross Revenue	\$3,872,474	\$4,800,673	\$5,237,597
Total Net Revenue	\$1,835,750	\$2,607,731	\$2,845,069
Total Operating Expenses	\$1,922,392	\$2,227,293	\$2,336,498
Net Income (Loss)	(\$86,642)	\$380,438	\$508,571

For the OR service component, in the projected revenue and expense statement, Form C, the applicants project revenues will exceed operating expenses in both the second and third operating years following completion of the proposed project, as shown in the table below.

Valleygate Dental Surgery Center of Fayetteville- Operating Rooms

	OY 1 (FFY 2018)	OY 2 (FFY 2019)	OY 3 (FFY 2020)
Total Gross Revenue	\$3,872,474	\$4,800,673	\$5,237,597
Total Net Revenue	\$951,938	\$1,269,457	\$1,303,302
Total Operating Expenses	\$1,008,465	\$1,127,833	\$1,136,891
Net Income (Loss)	(\$56,527)	\$141,624	\$166,411

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion subject to Condition #6, which can be found at the end of this document.

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

C- Both Applications

The 2016 State Medical Facilities Plan (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which includes Cumberland and Pitt counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

In response to petitions from Knowles, Smith & Associates and Triangle Implant Center, an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Demonstration Project (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state exemplifies the access and value Basic Principles by preventing a single area from having a concentration of dental OR facilities. The Project establishes a special need determination for up to four new separately licensed dental single specialty ambulatory surgical facilities with up to two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the four following regions:

- *Region 1: HSA IV*
- *Region 2: HSA III*
- *Region 3: HSA V and HSA VI*
- *Region 4: HSA I and HSA II*

Therefore, the 2016 SMFP defines the Region 3 service area as HSA V and HSA VI, which includes Anson, Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Edgecombe, Gates, Greene, Halifax, Harnett, Hertford, Hoke, Hyde, Jones, Lenoir, Martin, Montgomery, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Richmond, Robeson, Sampson, Scotland, Tyrell, Washington, Wayne and Wilson counties. Providers may serve residents of counties not included in their service area.

SCDP Greenville proposes to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with two operating rooms to be located in Greenville in Pitt County, which is located in Region 3: HSAs V and VI. The discussion regarding the requirements of the Demonstration Project need determination found in Criterion (1) is incorporated herein by reference. There are no existing or approved ambulatory surgery facilities dedicated to the performance of dental or oral surgical procedures requiring sedation anywhere in Region 3 or the state. Therefore, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved dental single specialty ambulatory surgical facilities. Consequently, the application is conforming to this criterion.

Valleygate proposes to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with two operating rooms to be located in Garner in Wake County, which is located in Region 3: HSAs V and VI. The discussion regarding the requirements of the Demonstration Project need determination found in Criterion (1) is incorporated herein by reference. There are no existing or approved ambulatory surgery facilities dedicated to the performance of dental or oral surgical procedures requiring sedation anywhere in Region 3 or the state. Therefore, the applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved dental single specialty ambulatory surgical facilities. Consequently, the application is conforming to this criterion.

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

C- Both Applications

SCDP Greenville. In Section VII.2, page 172, the applicant states that it will contract with Papillon Management, LLC, which will employ the staff for the proposed facility. In Section VII.2, page 173, the applicant provides the proposed staffing for the facility in OY2 (FFY2019), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Registered Nurses	1.5
Physician Assistant	0.5
Dental Assistant I	1.5
Dental Assistant II	2.0
Office Administration	2.5
Pediatrician	1.0
Housekeeping/maintenance and technical support	1.5
TOTAL	11.5

Source: Table VII.2, page 173.

In Section VII.3, pages 173-174, and Section VII.7, page 177, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 11 contains a copy of a letter from Uday Reebye, MD, DMD expressing his agreement to serve as the Medical Director for the proposed facility. Exhibit 29 of the application contains copies of letters from area dental professionals expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

Valleygate. In Section VII.2, page 182, the applicants state that they project a total of 10.88 full-time equivalent (FTE) positions at Valleygate in OY2. In Section VII.2, page 182, the applicant provides the proposed staffing for the facility in OY2 (FFY2019), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrators	2.00
Registered Nurses	1.17
Surgical Technicians	2.20
Certified Registered Nurse Anesthetists	Contracted
Non-health professionals/technical personnel	5.51
TOTAL	10.88

Source: Table VII.2, page 182.

In Section VII.3, pages 183-184, and Section VII.7, page 190, the applicants describe their experience and process for recruiting and retaining staff. Exhibit 36 contains a copy of a letter from Faith McGibbon, DDS, expressing her interest in serving as the Clinical Director of Valleygate. Exhibits 26 and 37 of the application contain copies of letters from area dental professionals expressing support for the proposed project. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C- Both Applications

SCDP Greenville. In Section II.2, pages 55-56 the applicant describes the manner in which it will provide the necessary ancillary and support services. In Section V.2, page 145, the applicant states its intention to establish transfer agreements with Vidant Medical Center. Exhibit 13 contains a copy of a letter from the applicant to Vidant Medical Center indicating the intention to establish transfer agreement as well as a sample copy of a proposed transfer agreement. See also Exhibits 2 and 7 for copies of the proposed management agreement and letters of intent from providers of anesthesia, radiology, laboratory and oral pathology services. Exhibit 29 of the application contains copies of letters from area dental professionals expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

Valleygate. In Section II.2, pages 38-39 the applicants describe the manner in which they will provide the necessary ancillary and support services. In Section V.2, page 149, the applicants states their intention to establish transfer agreements with area hospitals. Exhibit 15 contains copies of letters from the applicants to area hospitals indicating the intention to establish a transfer agreement. See also Exhibits 1, 10, 11 and 12 for copies of the proposed management agreement and letters of intent from various ancillary and support services providers stating their willingness to provide services. Exhibits 26 and 37 of the application

contain copies of letters from area dental professionals expressing support for the proposed project. The applicants adequately demonstrate that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C-Both Applications

SCDP Greenville proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in 9,868 square feet of leased space in an existing building at 1720 West Arlington Blvd in Greenville. In Exhibit 27, the architect certifies that the construction costs are projected to be \$2,428,088. This cost is consistent with the costs reported by the applicant in Section VII.1, page 183. In Section III, pages 124-125 and in Section XI.8, page 197, the applicant discusses the features and methods that will be used to maintain energy efficient operations and sustainability and contain costs of

utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in 10,708 square feet of a new building to be located at 2038 Litho Place in Fayetteville. In Exhibit 40, the architect certifies that the construction costs are projected to be \$3,286,852. This cost is consistent with the site and construction costs reported by the applicants in Section VIII.1, page 195. In Section III, pages 116-117 and in Section XI.8, page 218, the applicants discuss the features and methods that will be used to maintain energy efficient operations and sustainability and contain costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA- Both Applications

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA- Both Applications

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C- Both Applications

SCDP Greenville. In Section VI.14, pages 167, the applicant projects the following payor mix for the proposed dental ambulatory surgical facility in OY2 (FFY 2019):

SCDP Greenville Projected Payor Mix OY2 (10/1/2018-9/30/2019)	
Payor	Cases as % of Total Cases
Charity Care	4.2%
Self-Pay	10.1%
Medicaid*	63.9%
Private Insurance	21.8%
Total	100.0%

*Includes Health Choice

As shown in the table above, the applicants project that 63.9% of all cases will be covered by Medicaid. However, the applicants state that the Medicaid payor category includes Health Choice. Health Choice is a program for individuals who are under the age of 21 and do not qualify for Medicaid. On page 167 of the application, SDCP states that of the 63.9% Medicaid total, 36.9% is for individuals under the age of 21 and 78.1% is for individuals 21 years old or older. On pages 138-139, the applicant states that included in the Medicaid/Health Choice payor category for OY2 (FY 10/1/2018 – 9/30/2019) there will be 346 patients under 21 and 1,388 patients 21 or older and the total overall number of patients will be 2,715 (938+1,777=2,715). With the information available, it is not possible to determine how many of the 346 patients under 21 will be Medicaid patients and how many will be Health Choice patients. For purposes of determining a Medicaid percentage, if all 346 patients under 21 are not included, that leaves 1,388 Medicaid patients out of a total of 2,715 patients in OY2, or 51.1% (1,388 / 2,715 = .5112 or 51.1%). The applicant demonstrated that medically underserved groups will have adequate access to the proposed services. Moreover, the projected payor mix is consistent with the requirements in Table 6D in the 2016 SMFP. Therefore, the application is conforming to this criterion.

Valleygate. In Section VI.14, pages 176, the applicants provide the projected payor mix for the proposed dental ambulatory surgical facility in OY2 (FFY2019):

Valleygate Dental Surgery Center Projected Payor Mix OY2 (10/1/2018-9/30/2019)	
Payor	Cases as % of Total Cases
Self-Pay / Indigent*	5.3%
Commercial Insurance	5.4%
Medicare / Medicare Managed Care	0.0%
Medicaid	88.5%
Military	0.9%
Total	100.0%

*In Section III.4, page 111, and Section VI.14, page 177, the applicants state that uninsured patients are considered charity care patients.

On pages 176-180, the applicants describe their assumptions and methodology regarding their projected payor mix, which they state is based on their own historical experience, the experience of providers who are expected to refer patients to the proposed facility and experience of other clinics. The applicants demonstrated that medically underserved groups will have adequate access to the proposed services. Moreover, the projected payor mix is consistent with the requirements in Table 6D in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C- Both Applications

SCDP Greenville. In Section VI.9, pages 164-165, the applicant describes the range of means by which persons will have access to the proposed facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

Valleygate. In Section VI.9, pages 172-173, the applicants describe the range of means by which persons will have access to the proposed facility. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

- 14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C- Both Applications

SCDP Greenville. In Section V.1, page 143-146, the applicant states it intends to establish relationships with area health professional training programs. Exhibit 22 contains copies of letters from the ECU School of Dental Medicine and the UNC School of Dentistry expressing

support for the proposed project and their intention to establish a clinical training agreement with the applicant. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

Valleygate. In Section V.1, pages 147-148, the applicants state they intend to establish relationships with area health professional training programs. Exhibit 34 contains letters from the Chancellor of University of North Carolina Pembroke, the Director, OIC of the Advanced Education in General Dentistry (AEGD) Program at Fort Bragg, the Director of Education of Miller-Motte College in Fayetteville and a copy of an affiliation agreement between FTCC and Village Family Dental all regarding utilizing the proposed facility as a clinical training site. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C- Both Applications

The 2016 State Medical Facilities Plan (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3: HSAs V and VI, which include Pitt and Cumberland counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project
In response to petitions from Knowles, Smith & Associates and Triangle Implant Center, an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Demonstration Project (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state exemplifies the access and value Basic Principles by preventing a single area from having a concentration of dental OR facilities. The Project establishes a special need determination for up to four new separately licensed dental single specialty ambulatory surgical facilities with up to two operating rooms each, such that there is a need identified for one new ambulatory surgical facility in each of the four following regions:

- *Region 1: HSA IV*

- *Region 2: HSA III*
- *Region 3: HSA V and HSA VI*
- *Region 4: HSA I and HSA II*

Therefore, the 2016 SMFP defines the Region 3 service area as HSAs V and VI, which includes Anson, Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Edgecombe, Gates, Greene, Halifax, Harnett, Hertford, Hoke, Hyde, Jones, Lenoir, Martin, Montgomery, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Richmond, Robeson, Sampson, Scotland, Tyrell, Washington, Wayne and Wilson counties. Providers may serve residents of counties not included in their service area.

SCDP Greenville proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Greenville (Pitt County). In Section III.1, pages 91-100, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The development of SCDP of Greenville as proposed is needed to enhance the quality of care, access to and value of such surgical services for residents of Region 3 as described in the sections below....

Expertise and training is a fundamental cornerstone of the proposed delivery model at SCDP of Greenville. As evidenced by the credentialing policy included in Exhibit 18, all professionals practicing at SCDP of Greenville, including dentists, oral and maxillofacial surgeons, dental specialists, anesthesiologists, and dental assistants, will be required to adhere to strict credentialing guidelines with oversight from an external Credentialing Committee. ... This is to ensure that quality care is always provided to the patients utilizing services at the facility....

The proposed model will allow a broader range of qualified dental professionals to access much needed surgical services for their patients in a timely manner....

The proposed project will enhance access to dental care for historically underserved patients, including charity care and Medicaid patients, as well as patients whose general dentist has historically struggled to obtain access to existing operating rooms. ... Further, by proposing to perform cases requiring sedation or anesthesia in a licensed facility, SCDP of Greenville is expanding access to patients whose insurance may not have historically covered the cost of these services....

The proposed project will also enhance the cost-effectiveness of dental and oral surgical procedures. Pediatric dentists and oral and maxillofacial surgeons who may have previously performed their cases in a hospital-based operating room will now have a more appropriate and cost-effective setting in which to provide care. As a freestanding ASC, SCDP of Greenville will be able to provide care at a lower cost than hospital-based operating rooms. Further, SCDP of Greenville will not have hospital-

based expenses allocated to surgery services, the only expenses are those generated directly by the services provided by SCDP of Greenville. As a result, patients and payors will not incur charges associated with hospital-based care, resulting in significantly lower co-payments, and will have more timely access and quality care.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will provide quality services. The discussion regarding quality found in Criterion (1) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room in Fayetteville (Cumberland County). In Section V.7, pages 159-162, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state,

“The proposed project will offer competition by providing a completely new clinical concept. Existing operating rooms will still be able to compete with the proposed Valleygate Dental Surgery Center of Fayetteville, but the proposed facility will require others to compete in both cost and quality. It will create a better option for pediatric dental surgery and expand access for dental treatments for adults in a safe, efficient environment. ...

Competitive access features include cost, charity care levels, Medicaid and military payment acceptance, and service features.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will provide quality services. The discussion regarding quality found in Criterion (1) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA- Both Applications

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA- Both Applications

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2016 State Medical Facilities Plan, no more than one Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3 (HSAs V and VI) may be approved in this review. Because the two applications in this review collectively propose two Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects with a total of four operating rooms to be located in Region 3, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Valleygate, Project I.D. # J-11076-16, is approved and the other application, submitted by SCDP of Greenville, is denied.

Geographic Accessibility

Region 3: HSAs V and VI covers 44 counties. SCDP Greenville would be located in Greenville in Pitt County and Valleygate would be located in Fayetteville in Cumberland County. The following table compares the two cities and the two counties.

Population	Pitt County	Cumberland County	Greenville	Fayetteville
<18	38,614	87,840	na	na
18-64	116,000	205,315	na	na
65+	19,810	36,248	na	na
Total	174,424	329,403	87,436	208,373

Source: NCOBM for July 2014

As shown in the table above, as of July 2014, Cumberland County had 154,979 more residents than Pitt County and Fayetteville had 120,937 more residents than Greenville. Therefore, the application submitted by Valleygate is the most effective with regard to geographic accessibility to the largest population.

Access by Underserved Groups

The following table shows each applicant's projected cases to be provided to Charity Care and Medicaid recipients in the third full fiscal year of operation following completion of the project, based on the information provided in the applicants' pro forma financial statements (Form D). Generally, the application proposing to serve the higher numbers of Charity Care and Medicaid patients is the more effective alternative with regard to this comparative factor.

CHARITY CARE CASES OPERATING YEAR 3	Projected Total Cases Provided to Charity Care Recipients	Projected Percentage of Total Cases Provided to Charity Care Recipients
APPLICANT		
SCDP Greenville	127	4.2%
Valleygate	219	5.3%

MEDICAID CASES OPERATING YEAR 3	Projected Total Cases Provided to Medicaid Recipients	Projected Percentage of Total Cases Provided to Medicaid Recipients
APPLICANT		
SCDP Greenville	1,927	63.9%
Valleygate	3,677	88.5%

Source: SCDP Greenville cases by payor category are from Form D, page 205 of the application. Valleygate projected cases by payor category are from Form D, pages 229, 232, and 235 of the application. In Section III.4, page 111, and Section VI.14, page 177, Valleygate states all uninsured or self pay patients are considered charity care patients.

As shown in the tables above, Valleygate projects the highest number of cases to be provided to Charity Care and Medicaid recipients. Moreover, if SCDP Greenville’s under age 21 Health Choice patients are excluded (which means also excluding the under age 21 Medicaid patients because there is insufficient information to separate them, the Medicaid percentage for SCDP Greenville would decrease to 51.1%. Therefore, the application submitted by Valleygate is the most effective alternative with regard to access by Medicaid and charity care recipients.

Projected Average Gross Revenue per Case

The following table shows the projected gross revenue per case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form B). Generally, the application proposing the lowest average gross revenue per case is the more effective alternative with regard to this comparative factor.

Third Operating Year	SCDP Greenville	Valleygate
Gross Revenue	\$5,910,908	\$5,237,597
Cases	3,016	4,156
Gross Revenue/Case	\$1,960	\$1,260

Source: SCDP Greenville projected gross revenues and cases are from Form B, page 202 of the application. Valleygate projected gross revenues are from Form B, page 227, and projected cases are from Section IV.1, page 132 of the application.

As shown in the table above, Valleygate projects the lowest average gross revenue per case in the third operating year. The application submitted by Valleygate is the most effective alternative with regard to projected average gross revenue per case.

Projected Average Net Revenue per Case

The following table shows the projected net revenue per case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form B). Generally, the application proposing the lowest average net revenue per case is the more effective alternative with regard to this comparative factor.

Third Operating Year	SCDP Greenville	Valleygate
Net Revenue	\$3,286,914	\$2,845,069
Cases	3,016	4,156
Net Revenue/Case	\$1,090	\$685

Source: SCDP Greenville projected net revenues and cases are from Form B, page 202 of the application. Valleygate projected net revenues are from Form B, page 227, and projected cases are from Section IV.1, page 132 of the application.

As shown in the table above, Valleygate projects the lowest average net revenue per case in the third operating year. The application submitted by Valleygate is the most effective alternative with regard to projected average net revenue per case.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form B). Generally, the application proposing the lowest average operating expense per case is the more effective alternative with regard to this comparative factor.

Third Operating Year	SCDP Greenville	Valleygate
Total Operating Expenses	\$2,981,050	\$2,336,498
Cases	3,016	4,156
Operating Expense/Case	\$988	\$562

Source: SCDP Greenville projected operating expenses and cases are from Form B, page 202 of the application. Valleygate projected operating expenses are from Form B, page 227, and projected cases are from Section IV.1, page 132 of the application.

As shown in the table above, Valleygate projects the lowest average operating expense per case in the third operating year. The application submitted by Valleygate is the most effective alternative with regard to projected average net revenue per case.

SUMMARY

The following is a summary of the reasons the proposal submitted by Valleygate is determined to be the most effective alternative in this review:

- Valleygate proposes the most effective alternative with respect to geographic accessibility.
- Valleygate projects the highest number of cases to be provided to Charity Care and Medicaid recipients. See Comparative Analysis for discussion.
- Valleygate projects the lowest average gross revenue per case in the third operating year. See Comparative Analysis for discussion.
- Valleygate projects the lowest average net revenue per case procedure in the third operating year. See Comparative Analysis for discussion.
- Valleygate projects the lowest average operating expense per case in the third operating year. See Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by SCDP of Greenville is determined to be a less effective alternative in this review than the approved applicant.

- SCDP of Greenville proposes the least effective alternative with respect to geographic accessibility.
- SCDP of Greenville projects the lowest number of cases to be provided to Charity Care and Medicaid recipients. See Comparative Analysis for discussion.
- SCDP of Greenville projects the highest average gross revenue per case in the third operating year. See Comparative Analysis for discussion.
- SCDP of Greenville projects the highest average net revenue per case in the third operating year. See Comparative Analysis for discussion.
- SCDP of Greenville projects the highest average operating expense per case in the third operating year. See Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by Valleygate, Project I.D. #J-11176-16, is the most effective alternative proposed in this review for the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 3 (HSA V and VI) and is approved. The approval of the application submitted by SCDP of Greenville would result in Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects in excess of the need determination for Region 3. Consequently, the application submitted by SCDP of Greenville is denied.

The application submitted by Valleygate is approved subject to the following conditions.

- 1. Valleygate Dental Surgery Center of Fayetteville, LLC and VFD Real Estate Partners, LLC shall materially comply with all representations made in the certificate of need application.**

- 2. Valleygate Dental Surgery Center of Fayetteville, LLC and VFD Real Estate Partners, LLC shall develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with no more than two operating rooms and two procedure rooms.**
- 3. Valleygate Dental Surgery Center of Fayetteville, LLC and VFD Real Estate Partners, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
- 4. Valleygate Dental Surgery Center of Fayetteville, LLC and VFD Real Estate Partners, LLC shall comply with all applicable criteria in Table 6D in the 2016 State Medical Facilities Plan.**
- 5. Prior to issuance of the certificate of need, the applicants shall provide a projection for each of the first three full federal fiscal years of operation of the projected number of patients for the following payor types, broken down by age (under 21, 21 and older): (i) charity care; (ii) Medicaid; (iii) TRICARE; (iv) private insurance; (v) self-pay; and (vi) payment from other sources.**
- 6. Prior to the issuance of the certificate of need Valleygate Dental Surgery Center of Fayetteville, LLC shall provide documentation of the availability of funds for the capital and working capital needs of the project.**
- 7. Valleygate Dental Surgery Center of Fayetteville, LLC and VFD Real Estate Partners, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**