

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: Mike McKillip

Assistant Chief: Martha Frisone

COMPETITIVE REVIEW

Project ID #: J-11170-16
Facility: Surgical Center for Dental Professionals of Raleigh
FID #: 160154
County: Wake
Applicant: Surgical Center for Dental Professionals of Raleigh, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in Wake County pursuant to the demonstration project need determination in the 2016 SMFP

Project ID #: J-11175-16
Facility: Valleygate Dental Surgery Center of Raleigh
FID #: 160157
County: Wake
Applicant: Valleygate Dental Surgery Center of Raleigh, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure rooms in Wake County pursuant to the demonstration project need determination in the 2016 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

C – SCDP of Raleigh
 CA – 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 I: HSA IV, which includes Wake County. 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>	Value <i>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>	Access <i>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>	Value <i>Implementing this innovation through a demonstration project enables the State Health 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 professional 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	<p><i>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.</i></p>	<p>Value <i>Performing at least a minimum number of surgical procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.</i></p>
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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 I: HSA IV, which includes Wake County. 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 to be located in Wake County.

Surgical Center for Dental Professionals of Raleigh, LLC [SCDP of Raleigh] proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms to be located on Century Drive in Raleigh (Wake County).

Need Determination

SCDP of Raleigh’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 I: HSA IV, which includes Wake County. Also, the application is consistent with the requirements in Table 6D in the 2016 SMFP, as follows:

1. In Section II.1, page 50, the application contains a description of the percentage ownership interest in the facility by each oral surgeon and dentist.
2. In Section II.1, pages 50-51, the applicant states the proposed facility will provide open access to non-owner and non-employee oral surgeons and dentists.
3. In Section II.1, page 51, the applicant states the facility will provide only dental and oral surgical procedures requiring sedation.
4. In Section II.1, page 51, the applicant states the proposed facility will obtain a license no later than one year from the effective date of the certificate of need.

5. In Section II.1, pages 51-52, the applicant states the proposed facility will be certified by the Centers for Medicare and Medicaid Services (CMS), and commits to continued compliance with CMS conditions of participation.
6. In Section II.1, page 52, the applicant states the proposed facility will provide care to underserved dental patients. In Section VI.14, page 166, the applicant projects that more than 3 percent of the total number of patients served each year will be charity care patients and more than 30 percent of the total number of patients served each year will be Medicaid recipients.
7. In Section II.1, page 52, the applicant states the proposed facility will obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC) and/or The Joint Commission (TJC), and commits to continued compliance with their respective standards.
8. In Section II.1, page 53, the applicant states 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. In Section II.1, page 53, the applicant states the proposed facility will meet all reporting, monitoring and evaluation requirements of the demonstration project, as set forth by the Agency.
10. In Section IV.1, page 137, the applicant provides a projection for each of the first three full federal fiscal years of operation (FFY2018-FFY2020) 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.
11. In Section IV.1, page 135, the applicant projects the proposed facility will perform more than 900 surgical cases per operating room during the third full federal fiscal year of operation (FFY2020).

Policies

Policy GEN-3

SCDP of Raleigh 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 III.1, pages 91-92, Section III.4, page 120, Section II.8, pages 60-62, and referenced exhibits. 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.1, pages 92-98, Section III.4, pages 122-124, Section VI, pages 153-170, and referenced exhibits. 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 healthcare value in Section III.1, page 98, and Section III.4, page 124. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare 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, page 124, and Section XI.8, page 196, 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 and water conservation. Therefore, the application is consistent with Policy GEN-4.

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

Valleygate Dental Surgery Center of Raleigh, LLC [Valleygate] proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room to be located on Vandora Springs Road in Garner (Wake 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 I: HSA IV, which includes Wake County. Also, the application is consistent, as conditioned, with the requirements in Table 6D in the 2016 SMFP, as follows:

1. In Section I.12, page 7, the application contains a table showing the percentage ownership interest in the facility by each oral surgeon and dentist.
2. In Section III.4, page 97, the applicant states the proposed facility will provide open access to non-owner and non-employee oral surgeons and dentists.
3. In Section III.4, page 97, the applicant states the facility will provide only dental and oral surgical procedures requiring sedation.
4. In Section III.4, page 98, the applicant states the proposed facility will obtain a license no later than one year from the effective date of the certificate of need.

5. In Section III.4, page 98, the applicant states the proposed facility will be certified by the Centers for Medicare and Medicaid Services (CMS), and commits to continued compliance with CMS conditions of participation.
6. In Section III.4, page 98, the applicant states the proposed facility will provide care to underserved dental patients. In Section VI.14, page 159, the applicant projects that more than 3 percent of the total number of patients served each year will be charity care patients and more than 30 percent of the total number of patients served each year will be Medicaid recipients.
7. In Section III.4, page 99, the applicant states the proposed facility will obtain accreditation no later than one year after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), and commits to continued compliance with their respective standards.
8. In Section III.4, page 100, the applicant states 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. In Section III.4, page 101, the applicant states the proposed facility will meet all reporting, monitoring and evaluation requirements of the demonstration project, as set forth by the Agency.
10. In Section III.4, page 101, the applicant states, *“The applicant agrees to provide information required by this criterion for each of the first three full fiscal years of operation.”* The payor mix projections provided by the applicant in Section VI.14, page 163, show only the applicant’s payor mix projections for Year 2 (FFY2019), and not for the first three full federal fiscal years. Also, the applicant’s payor mix projections show *“SelfPay/Indigent/Charity”* as one category, and *“Medicare/Medicare Managed Care,” “Commercial Insurance,” “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). However, the Agency’s calculations for Year 3 were not identical to those provided by the applicant in its response to comments. 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 of the 2016 SMFP. As such, the applicant can be and is conditioned to provide the payor mix percentages for Years 1 and 3 that were omitted from the application.
11. In Section IV.1, page 115, the applicant projects the proposed facility will perform more than 900 surgical cases per operating room during the third full federal fiscal year of operation (FFY2020).

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 III.4, page 104, Section II.8, pages 33-34, and referenced exhibits. 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 103, Section VI, pages 147-164, and referenced exhibits. 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 healthcare value in Section III.4, page 102. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare 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, page 105, and Section XI.8, page 198, 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 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, as conditioned, 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 I: HSA IV, which includes Wake County. 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 I: HSA IV 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 are conforming to all statutory and regulatory review criteria, both applications cannot be approved.

SCDP of Raleigh's application is conforming to the need determination, Policy GEN-3 and Policy GEN-4. Valleygate's application is conforming with Policy GEN-3, Policy GEN-4 and, as conditioned, with the need determination in the 2016 SMFP. Therefore, both applications are conforming or conditionally 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 1 service area as HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. Providers may serve residents of counties not included in their service area.

SCDP of Raleigh. The applicant, SCDP of Raleigh, proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in leased space in a new office building located at 2209 Century Drive in Raleigh (Wake County). In Section I.10, pages 6-7, the applicant states SCDP of Raleigh will lease the space from Solferino North Properties, LLC, and management of the facility will be contracted to Papillon Management, LLC. SCDP of Raleigh 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 Raleigh proposes to lease 10,542 square feet of space, primarily on the second floor in a building located at 2209 Century Drive in Raleigh, which is currently under development, for the development of the proposed dental ASC. ... The primary functions of the proposed ASC will be located in 8,534 square feet on the second floor of the building. This floor will house two licensed operating rooms, six 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 six procedure rooms, and are shaded orange on the proposed line drawing (Exhibit 10). Also included in this space are a staff lounge, changing room, and patient toilet facilities. Non-clinical support spaces on the second floor including the elevator lobby (access from the first floor of the building), receiving and registration, patient waiting, medical records, and toilets are shaded yellow on the proposed line drawings (Exhibit 10). Medical gases and a private elevator lobby and elevator that lead to the post-operative area on the second floor will be located in 378 square feet of leased space on the first floor of the building as noted in the first floor line drawings included in Exhibit 10. Finally, administrative space, including offices, a conference/training room, and open work area will be located within 1,630 square feet of leased space on the third floor of the building as noted in the third floor line drawings included in Exhibit 10.”

Population to be Served

In Sections III.6, page 126, the applicant provides the projected patient origin for the proposed facility for the first two operating years (FFY2018-2019), as summarized in the table below.

SCDP of Raleigh Projected Patient Origin

County (HSA)	Year 1 Projected Patients FFY2018	Year 2 Projected Patients FFY2019	Projected Percent of Total Patients
Wake (IV)	2,171	2,442	41.3%
Chatham (IV)	970	1,091	18.5%
Orange (IV)	645	726	12.3%
Caswell (II)	518	583	9.9%
Durham (IV)	394	443	7.5%
Johnston (IV)	212	239	4.0%
Granville (IV)	92	104	1.8%
Franklin (IV)	79	89	1.5%
Alamance (II)	67	76	1.3%
Halifax (VI)	38	43	0.7%
Moore (V)	29	32	0.5%
Guilford (II)	19	22	0.4%
Vance (IV)	10	11	0.2%
Warren (IV)	6	7	0.1%
TOTAL	5,251	5,908	100.0%

Source: Table on page 126.

In Section III.6, page 126, with regard to its assumptions for projected patient origin, the applicant states,

“For the users or referrers that could provide internal data, SCDP of Raleigh 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 SCDP of Raleigh, for analysis, SCDP of Raleigh assumed their patients would originate from the county where their practice is currently located. ... SCDP of Raleigh 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.”

The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describe the factors which it states support the need for the proposed project, including:

- The lack of accessibility to operating rooms at hospitals and multispecialty ambulatory surgical facilities by dental professionals (pages 73-82).
- Historical and projected population growth in the Region 1 service area (pages 82-87).

- The dentist shortage and the need for continuing education opportunities for dentists and oral surgeons and training opportunities for dental students that the proposed facility would provide (pages 88-90).
- Historical use rates per 1,000 population for dental and oral surgical cases requiring sedation experienced by the applicant's existing Triangle Implant Center offices in Durham, Alamance and Wilson counties (pages 103-109).

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

Projected Utilization

In Section IV.1, page 135, the applicant provides the projected utilization for the operating rooms and procedure rooms at its proposed facility for the first three years of operation following completion of the project (FFY2018-FFY2020), which is summarized below.

**SCDP of Raleigh
 Projected Utilization (FFY2018-FFY2020)**

	Year 1 FFY2018	Year 2 FFY2019	Year 3 FFY2020
Operating Room Utilization			
Operating Room Cases	1,600	1,800	2,000
Number of Operating Rooms	2	2	2
Operating Room Cases/Operating Room	800	900	1,000
Procedure Room Utilization			
Procedure Room Cases	3,651	4,108	4,564
Number of Procedure Rooms	6	6	6
Procedures/Procedure Room	609	685	761

Source: Table on page 135 of the application.

As shown in the above table, the applicant projects the proposed facility will perform 2,000 cases in the two operating rooms, or 1,000 cases in each operating room, in the third operating year (FFY2020), which exceeds the annual utilization standard of 900 surgical cases per operating room required in Table 6D in the 2016 SMFP. The applicant's utilization projections are based on support letters from dental professionals contained in Exhibit 29 of the application. The support letters in Exhibit 29 include estimates by those dental professionals of the number of dental procedures for patients requiring sedation they will perform each month at the proposed dental ASF. In Section III.1(b), pages 109-110, the applicant states,

“As demonstrated in the support letters provided in Exhibit 29 and summarized in the table [on page 110 of the application], the users of SCDP of Raleigh intend to perform between 6,564 and 7,320 cases annually at the proposed facility once it is operational. Notwithstanding the discussion above regarding the current and projected need for the proposed facility based on estimated use rates and population growth over time, the cases projected by the users of the proposed facility are

conservatively based on their current volume, which they expect to perform at SCDP of Raleigh, and which is more than sufficient to demonstrate the need for the proposed project....

Based on the table above and the letters of support in Exhibit 29, SCDP of Raleigh's users project to perform 347 to 410 cases per month at the proposed facility or 4,164 to 4,920 cases per year."

In addition to the letters of support discussed above, the applicant's utilization projections are based on letters submitted by Piedmont Health, which operates community health centers in the applicant's proposed service area. The letters from Piedmont Health, which are contained in Exhibit 29, estimate that it will refer 200 patients per month from its community health centers in Carrboro, Moncure, Prospect Hill, and Siler City to the proposed dental ASF. On pages 111-112, the applicant states,

"In addition to the projected cases by user projected above, Piedmont Health, a sliding-scale patient-centered medical home with eight locations in central North Carolina has provided letters of support committing referrals to SCDP of Raleigh. Piedmont Health has served residents of central North Carolina for over 44 years including patients in 14 counties who are primarily uninsured or Medicaid. Its designated service areas are: Alamance, Caswell, Chatham, Lee, Orange, Person, and Randolph counties. Four of its eight locations provide dental services. As noted in the general letter of support signed by Brian Toomey, Chief Executive Officer, Piedmont Health's dentists routinely experience difficulty referring patients in need of dental procedures which require sedation or general anesthesia.

As shown in its letters of support, Piedmont Health projects to refer in total 200 cases per month, or 2,400 cases annually, to SCDP of Raleigh for dental cases [sic] procedures requiring sedation. These 200 cases are expected to be comprised of 50 referrals per month from four Piedmont Health locations: Carrboro Community Health, Moncure Community Health Center, Prospect Hill Community Health Center, and Siler City Community Health Center. Please note that Prospect Hill Community Health Center is located in Caswell County, which is adjacent to Region 1. Given the proposed location of SCDP of Raleigh, Piedmont Health's leadership believes it is reasonable for patients served at this site to travel to SCDP of Raleigh for their dental cases requiring sedation.

Based on the support described above, SCDP of Raleigh conservatively projects that it will provide 6,564 cases annually by the third project year, which is based on the low annual estimate for its users of 4,164 cases plus 2,400 annual cases referred by Piedmont Health."

With regard to the projected allocation of the cases between the operating rooms and procedure rooms, the applicant projects that 2,000 of the cases will be performed in the two

operating rooms and the remaining 4,564 cases will be performed in the six procedure rooms. On page 112, the applicant states,

“Based on its experience providing dental and oral surgical procedures requiring sedation, SCDP of Raleigh believes that most of these cases would be appropriate to be performed in either the two proposed operating rooms or in the six proposed procedure rooms. Patients will be priority scheduled in the operating rooms based on the request of the user. SCDP of Raleigh believes it is reasonable to estimate that each operating room will provide 1,000 cases annually and that the remainder of the facility’s cases will be performed in one of the six procedure rooms. As such, the six procedure rooms are expected to provide 4,564 cases annually or 761 cases per room.

While the procedure rooms will be similar in capability to the operating rooms, SCDP of Raleigh expects them to be used slightly less, on average, than the operating rooms for a few reasons. First, if special requests are made by users for a particular room, it is likely to be for one of the operating rooms; thus, they will likely be used more than the procedure rooms, based on availability. Second, one of the procedure [sic] rooms will be more specialized in that it will include a fixed microscope and cases requiring that equipment will require and have priority for the use of that room. Thus SCDP expects the average capacity and the average number of cases performed in each procedure room to be slightly less than that performed in each operating room.”

Also, the applicant’s projections include the assumption that utilization will “ramp up” over the first three operating years. On page 114, the applicant states,

“Rather than projecting growth between now and the third project year, SCDP of Raleigh conservatively projects the cases estimated by the users to be achieved in the third project year, not the first, following a ramp-up period. SCDP of Raleigh has therefore assumed that its volume will ramp up from PY1 to PY3, using conservative estimates of 80 percent and 90 percent of the total PY3 volume for PY1 and PY2, respectively.

	Year 1	Year 2	Year 3
<i>% Ramp-Up</i>	80%	90%	100%
<i>Operating Rooms</i>	1,600	1,800	2,000
<i>Procedure Rooms</i>	3,651	4,108	4,564
Total Facility	5,251	5,908	6,564

Exhibit 29 contains letters from 69 dental professionals in the proposed service area expressing support for the proposed project and their intention to perform, collectively, between 347 and 410 cases per month (4,164 to 4,920 cases, annually) at the proposed facility. Exhibit 29 also contains letters from Piedmont Health expressing their intention to refer 200 patients per month (2,400 annually) to the proposed facility. 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 69-117, 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 surgery specialty ambulatory surgical facility in Region 1.

Access

In Section VI.2, pages 153-156, the applicant states it is committed to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.14, page 166, the applicant projects that 47.1 percent of patients to be served will be Medicaid recipients. 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. The applicant, Valleygate, proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room in leased space in a building located at 958 Vandora Springs Road in Garner (Wake County). In Section I.10, pages 4-5, the applicant states Valleygate will lease the space from GK Murthy and Baratha L. Manne, and that management of the facility will be contracted to Knowles, Smith and Associates, LLP. In Section I.12, page 7, the applicant states Valleygate is a limited liability company whose members are seven dentists, each of whom holds a 14.3 percent ownership interest. The applicant states that each of the dentists is also an owner of Knowles, Smith and Associates. In Section II.1, page 19, the applicant describes the proposed project as follows:

“It will have two operating rooms, one procedure room, and an eight-unit pre- and post-surgery care area, which will include three 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. Three private rooms in the pre- and post-surgery area will support pre- and post-surgery care, history and physical examinations prior to admission, as well as 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 applicant proposes to develop one procedure room and three treatment rooms (“*dental treatment suites*”). On page 22, the applicant describes the procedure room as follows:

“This procedure room 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 room. This room will have the same sterile environment and be located with the operating rooms in the sterile core area ‘behind the yellow line.’ The procedure room will accommodate dental cases ranging from extractions and restorations under conscious sedation, to complex cases under general anesthesia.”

On page 22, the applicant describes the three 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 applicant states that typical procedures to be performed in the three treatment rooms will include tooth extractions, endodontic therapy (root canals), and dental crowns. On page 23, the applicant states,

“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 Sections III.6, page 107, the applicant provides 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
Wake (IV)	50.0%
Durham (IV)	18.8%
Johnston (IV)	9.2%
Harnett (V)	5.9%
Vance (IV)	3.6%
Lee (IV)	3.3%
Franklin (IV)	2.6%
Chatham (IV)	2.5%
Granville (IV)	2.1%
All Others*	2.0%
TOTAL	100.0%

Source: Table on page 107.

*The applicant states “All Others” includes Warren, Person, Orange and other counties within a 60-minute driving time radius around the proposed facility.

In Section III.6, page 107, the applicant states projected patient origin is based on the practice locations of the dentists that have committed to using the facility, expected referrals from community health centers, and the need for dental surgical services within the applicant’s market area. The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describe the factors which it states support the need for the proposed project, including:

- The incidence and prevalence of dental disease in children (pages 44-56).
- Barriers to access to dental and oral surgical services such as medical staff credentialing requirements and regulatory requirements (pages 60-66).
- The lack of access and regular availability of operating rooms at area hospitals (pages 63-64).
- The need for specialized dental surgical equipment (page 68).
- The need to reduce the incidence of dental-related emergency room visits (page 69).
- The need for dental surgical services for children of low-income families (pages 72-77).
- Shortages in dental health professional within the proposed service area (pages 77-79).

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

Projected Utilization

In Section IV.1, page 115, the applicant provides the projected utilization for the operating rooms and procedure rooms at its proposed facility for the first three years of operation following completion of the project (FFY018-FFY2020), which is summarized below.

**Valleygate
 Projected Utilization (FFY2018-FFY2020)**

	Year 1 FFY2018	Year 2 FFY2019	Year 3 FFY2020
Operating Room Utilization			
Operating Room Cases	1,756	1,938	1,937
Number of Operating Rooms	2	2	2
Operating Room Cases/Operating Room	878	969	969
Procedure Room Utilization			
Procedure Room Cases	573	706	917
Number of Procedure Rooms	1	1	1
Treatment Rooms			
Treatment Room Cases	177	201	217
Number of Treatment Rooms	3	3	3
Treatment Rooms Cases/Treatment Room	59	67	72

Source: Table on page 135 of the application.

As shown in the above table, the applicant projects the proposed facility will perform 1,937 cases in the two operating rooms, or 969 cases in each operating room, in the third operating year (FFY2020), which exceeds the annual utilization standard of 900 surgical cases per operating room as required in Table 6D in the 2016 SMFP.

In Section III.1(a), pages 80-91, and Section IV.1, pages 116-128, the applicant describes its methodology and assumptions for projecting utilization of the proposed facility.

Based on the applicant's experience in 2012, it assumes that 36.3 percent of Medicaid patients under age 9 will require a dental procedure under general anesthesia [See table on page 80]. Based on data from the North Carolina Division of Medical Assistance (DMA) for 2014, the applicant projects the total number of Medicaid beneficiaries under age 9 that will receive dental treatment each year from 2014 through 2020 by HSA [See table on page 83]. On page 84, the applicant applies the percentage that it assumes will require a dental procedure under general anesthesia (36.3%) to the total projected number of Medicaid patients under age 9 who will require dental services [See table on page 84]. Based on data from the Centers for Disease Control, the applicant assumes that the non-Medicaid patient population under age 9 will require dental procedures under general anesthesia at approximately half the rate at which Medicaid patients will require them [See table on page 85]. On page 86, the applicant combines the total projected number of Medicaid patients under age 9 who will require dental services under general anesthesia with total projected number of non-Medicaid patients under age 9 will require dental procedures under general anesthesia for each year from 2014 through 2020 by HSA [See table on page 86]. On page

87, the applicant estimates the percentage of dental surgery cases in operating rooms for patients over the age of 9 based on data provided by the DMA, as shown in the following table.

Table III.12 – Estimated Percent NC Medicaid Dental Surgery Cases Over Age Nine

Age Group	2015 Dental Surgery Cases in Hospitals or ASCs (b)
0 – 5	9,092
6 – 7	1,858
8 – 20	2,052
21+	1,257
Total	14,259
Percent 21 and Over (a)	8.82%

Notes: a: To be conservative, the applicant assumes percent Medicaid cases for 21 and older = estimated all payer percent for 9 and older.
 b: Provided by the NC Division of Medical Assistance

On page 88, the applicant states,

“To estimate the total population in need, divide the total need for patients under [age] nine from [the table on page 86 of the application] by one minus the estimate percent dental surgery cases in operating [sic] for individuals nine and over from [the table on page 87 of the application].

Table III.13 – Estimated Total Persons in Need of General Anesthesia Dental Surgery by Year

HSA	2014	2015	2016	2017	2018	2019	2020
<i>I</i>	9,228	9,172	9,117	9,062	9,009	8,956	8,904
<i>II</i>	13,131	13,066	13,001	12,937	12,873	12,809	12,746
<i>III</i>	13,914	13,924	13,936	13,947	13,960	13,974	13,988
<i>IV</i>	11,597	11,577	11,558	11,539	11,521	11,504	11,487
<i>V</i>	9,648	9,579	9,512	9,447	9,382	9,319	9,257
<i>VI</i>	8,194	8,100	8,007	7,917	7,827	7,740	7,653
Total	65,711	65,419	65,131	64,849	64,573	64,302	64,035

Source: Step 7, Table III.11 divided by (1 minus 8.82%).

On page 91, the applicant provides the following table showing the total projected number of patients who will require dental services under general anesthesia for each county in the applicant’s proposed market area from 2014 through 2020.

Table III.15 – Total Need: 9-County Service Area

	HSA	2014	2015	2016	2017	2018	2019	2020
<i>Chatham</i>	<i>IV</i>	366	361	357	352	348	343	339
<i>Durham</i>	<i>IV</i>	2,457	2,478	2,500	2,522	2,544	2,566	2,589
<i>Franklin</i>	<i>IV</i>	369	365	361	358	354	350	346
<i>Harnett</i>	<i>V</i>	797	798	799	800	801	802	802
<i>Granville</i>	<i>IV</i>	319	313	307	302	297	291	286
<i>Johnston</i>	<i>IV</i>	1,265	1,265	1,264	1,264	1,263	1,263	1,262
<i>Lee</i>	<i>IV</i>	472	468	464	460	457	453	449
<i>Vance</i>	<i>IV</i>	520	514	507	501	495	489	483
<i>Wake</i>	<i>IV</i>	4,870	4,861	4,852	4,842	4,833	4,824	4,815
Total		11,435	11,423	11,412	11,401	11,391	11,381	11,372

In Section IV.1, page 116, the applicant estimates that referral sources who have expressed an interest and support for the project would refer 2,429 dental surgical cases to the proposed dental ASF, annually, based on “*letters, person-to-person meetings, phone calls and emails.*” The applicant provides the following table on page 116 of the application.

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

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

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

On page 117, the applicant states that it then calculates “*the ratio of estimated cases from referral sources to the total estimated need in the nine counties from Section III.1(b) for 2015.*”

Table IV.3 – Ratio of Estimated Annual Cases to 2015 Estimated Need

<i>a</i>	<i>Cases Table IV.2</i>	<i>2,429</i>
<i>b</i>	<i>Nine-County Need 2015</i>	<i>11,423</i>
<i>c</i>	<i>Ratio of cases to need</i>	<i>21%</i>

Notes

a Table IV.2

b Table III.15

c a/b

Therefore, based on the applicant’s projection of the number of patients who will require dental services under general anesthesia for each county in the applicant’s proposed market area for 2015 [Shown in Table III.15 above], and the applicant’s estimate of the total number of referrals from the prospective referral sources identified in Table IV.2 above, the applicant projects its proposed dental ASF would have a market share of 21 percent of the total dental surgical cases from the proposed market area in 2015. On page 118, the applicant provides a table showing its market share projections for the first three operating years, which is shown below:

Table IV.4 – Estimated Valleygate DSCR Market Share of Need Treated by Year

<i>FY 2015</i>	<i>FY 2018</i>	<i>FY 2019</i>	<i>FY 2020</i>
<i>21%</i>	<i>22%</i>	<i>25%</i>	<i>27%</i>

With regard to its market share projection, on page 118, the applicant states,

“The modest growth of four percent market share after the first year and two percent market share [growth] after the second year is reasonable. LIP’s [licensed independent professionals] utilizing the proposed facility will be able to schedule patients in the facility in advance of opening. ... Valleygate DSCR will continue building relationships to support region-wide utilization starting in year one. The applicant expects some additional growth as patients and providers across the region become more aware of services after opening.”

On page 120, the applicant provides a table showing its projected market shares for the first three operating years applied to the applicant’s projected number of patients who will require dental services under general anesthesia for the applicant’s proposed market area, which are shown below:

Notes	Metric	FY 2018	FY 2019	FY 2020
<i>A</i>	<i>Need for Dental Surgery Cases in Hospitals and ASCs in the Proposed Service Area</i>	<i>11,391</i>	<i>11,381</i>	<i>11,372</i>
<i>B</i>	<i>Estimated Market Share</i>	<i>22.0%</i>	<i>25.0%</i>	<i>27.0%</i>
<i>C</i>	<i>Projected Cases Served</i>	<i>2,506</i>	<i>2,845</i>	<i>3,070</i>

Notes

a From Table III.15

b Table IV.4

c *a***b*

On page 121, the applicant provides a table showing its projected number cases that will be served in the three treatment rooms, based on the assumption that 7.05 percent of the total projected cases will be appropriate for those rooms. The applicant states,

“Multiply the percent of cases that will be adults (8.82%) by the percent of adults [sic] by the estimated percent who will not need general anesthesia.

*8.82% * 80% = 7.05% of total cases in treatment rooms for each of the first three project years.*

Multiply the total cases from Step 2, Table IV.6 by 7.05 to get total cases in treatment rooms for each of the first three project years.

Table IV.8 – Total Cases in Treatment Rooms

FY 2018	FY 2019	FY 2020
<i>177</i>	<i>201</i>	<i>217</i>

On page 122, the applicant states,

*“General anesthesia is often clinically indicated for special needs adults. To allow for both, recognizing that most of the literature indicates that general anesthesia for adults is less often necessary, the applicant assumes that 80 percent of the adults (persons over 21) treated in VDSCR will use the dental treatment rooms. Assuming that only this group uses the dental treatment rooms for cases, the applicant expects 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).”*

With regard to the projected allocation of the cases between the operating rooms and the procedure room, on page 122, the applicant states,

“Distribute remaining cases to operating rooms and procedure rooms [sic], assigning the highest ASA [American Society of Anesthesiologists] level cases to the operating rooms and distributing the remaining cases to operating room time not used by high acuity cases and then to the procedure room.

The applicant proposes two operating rooms and one procedure room. As described in Section II.1, the most acute patients will be scheduled only in operating rooms. The procedure room will be designed and equipped to support general anesthesia. To accommodate the highest acuity patients with early starts, the applicant plans to reserve at least the first half of the day in both operating rooms for the high ASA patients. ... For efficiency, and to maximize block scheduling opportunities, the applicant will schedule the remaining general anesthesia patients in both operating rooms and procedure rooms [sic].”

Based on the applicant’s assumptions regarding patient acuity levels, surgical case times, and room capacity [See tables on pages 123-127], the applicant projects the distribution of cases among the three room types for the first three operating years in a table on page 128, which is summarized below:

Projected Cases by Room Type	Number of Rooms	FY 2018	FY 2019	FY 2020
Operating Rooms	2	1,756	1,938	1,937
Procedure Room	1	573	706	917
Treatment Rooms	3	177	201	217
Total Cases		2,506	2,845	3,070

Source: Table on page 128 of the application.

As discussed above, the applicant’s projections of surgical cases that will be performed at the proposed dental ASF are based on its historical experience regarding the percentage of patients that will require a require a dental procedure under general anesthesia, and the total projected number of Medicaid patients under age 9 who will require dental services in the proposed service area based on DMA estimates and projected population growth in the proposed service area. The applicant projects utilization by non-Medicaid patients based on data from the CDC. The applicant’s estimates of dental surgery cases in operating rooms for patients over the age of 9 is based on data provided by the DMA. The applicant’s market share projections are supported by letters in Exhibits 26 and 33 from dental professionals and other healthcare providers in the proposed service area 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 applicant in Section III, pages 41-91, 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 surgery specialty ambulatory surgical facility in Region 1.

Access

In Section VI.2, pages 147-149, the applicant states it is committed to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as

underserved. In Section VI.14, page 159, the applicant projects that 88.5 percent of patients to be served will be Medicaid recipients. 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.

- (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 of Raleigh. In Section III.8, pages 127-131, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not meet the need for a facility where dental procedures that require sedation can be performed.
- Locate the Facility in Another Part of Region 1 – The applicant states that it determined that Raleigh was the best location because *“it is centrally located among the fastest growing counties of the region and is located within the largest municipality of the largest county within this region as well.”*
- Develop a Pediatric-Only Dental ASF – The applicant states that developing a pediatric-only dental ASF is not the most effective alternative because it would not promote access to dental procedures requiring sedation to both children and adults.

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 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 applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

Valleygate. In Section III.8, pages 109-111, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not address the lack of access to properly equipped operating rooms for pediatric dentists and their patients.
- Perform the Dental Procedures Requiring Anesthesia in Dental Offices – The applicant states that it rejected this alternative because performing these procedures in an operating room provides “*an enhanced level of safety*” and is more financially feasible than performing these procedures in a dental office.
- Locate the Facility in a Different Location in Region 1 - The applicant states that it rejected this alternative because the Wake County location is “*closest to the highest concentration of need in the region.*”
- Select a Different Scope of Services – The applicant states that its proposed scope of service is based on its determination that “*the primary driver of need for access to dental surgery, under general anesthesia, in a safe environment, is the needs of children.*”

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 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 applicant adequately demonstrates 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 of Raleigh. The applicant, SCDP of Raleigh, proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in leased space in a new office building located at 2209 Century Drive in Raleigh.

Capital and Working Capital Costs

In Section VIII.1, pages 181-182, the applicant states the total capital cost is projected to be as follows:

SCDP of Raleigh Project Capital Cost

Construction Contract	\$2,428,088
Fixed Equipment	\$725,927
Movable Equipment	\$95,000
Furniture	\$190,000
Architect & Engineering Fees	\$238,000
Financing Costs	\$25,000
Interest During Construction	\$250,000
TOTAL CAPITAL COST	\$3,952,015

Source: Table on pages 181-182 of the application.

In Section IX.1, page 187, the applicant states there will be \$198,034 in start-up expenses and \$569,805 in initial operating expenses, for total working capital required of \$767,839.

Availability of Funds

In Section VIII.3, page 182, the applicant states that the project capital costs will be funded by a loan from PNC Bank. In Section IX.2, page 187, the applicant states that the working capital will also be funded by a loan from PNC Bank. In Exhibit 25, the applicant provides a letter dated April 12, 2016, from a Vice President for PNC Bank documenting its intention to fund the capital and working capital costs for the proposed project with “\$5 million of secured financing.” The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for SCDP of Raleigh (Form B), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

SCDP of Raleigh

	FFY2018	FFY2019	FFY2020
Total Gross Revenue	\$10,291,172	\$11,578,794	\$12,864,455
Total Net Revenue	\$6,040,307	\$6,796,002	\$7,550,646
Net Revenue Per Case	\$1,150	\$1,150	\$1,150
Total Operating Expenses	\$3,708,195	\$3,939,830	\$4,161,841
Net Income (Loss)	\$2,332,112	\$2,856,172	\$3,388,805

The assumptions used by the applicant 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 utilization projections 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. The applicant, Valleygate, proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure rooms in leased space in a building located on Vandora Springs Road in Garner.

Capital and Working Capital Costs

In Section VIII.1, pages 178-179, the applicant states the total capital cost is projected to be as follows:

Valleygate Project Capital Cost

Site Costs	\$35,000
Construction Contract	\$2,352,179
Fixed Equipment	\$565,776
Movable Equipment	\$93,612
Furniture	\$57,693
Consultant Fees	\$305,000
Contingency (10%)	\$340,927
TOTAL CAPITAL COST	\$3,750,187

Source: Table on pages 178-179 of the application.

In Section IX.1, page 184, the applicant states there will be \$45,351 in start-up expenses and \$618,722 in initial operating expenses, for total working capital required of \$644,073.

Availability of Funds

In Section VIII.3, page 180, the applicant states that the project capital costs will be funded by a loan from First Citizens Bank. In Section IX.2, page 185, the applicant states that the working capital will also be funded by a loan from First Citizens Bank. In Exhibit 38, the applicant provides a letter dated April 13, 2016, from a Senior Vice President for First Citizens Bank documenting its intention to fund up to \$4 million in capital costs and up to \$1 million in working capital costs for the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for Valleygate (Form B), the applicant projects that revenues will exceed operating expenses in the second and third full fiscal years of operation of the project, as shown in the table below.

Valleygate			
	FFY2018	FFY2019	FFY2020
Total Gross Revenue	\$3,250,666	\$3,690,782	\$3,982,813
Total Net Revenue	\$1,581,722	\$2,020,454	\$2,192,331
Net Revenue Per Case	\$631	\$710	\$714
Total Operating Expenses	\$1,770,477	\$1,946,425	\$2,023,944
Net Income (Loss)	(\$188,755)	\$74,030	\$168,387

The assumptions used by the applicant 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 utilization projections 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.

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

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 I: HSA IV, which includes Wake County. 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 1 service area as HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. Providers may serve residents of counties not included in their service area.

SCDP of Raleigh. The applicant proposes to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with two operating rooms to be located in Raleigh in Wake County, which is located in Region I: HSA IV. 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 1 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. The applicant 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 I: HSA IV. 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 1 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.

- (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 of Raleigh. In Section VII.2, page 171, 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 172, the applicant provides the proposed staffing for the facility in operating year 2 (FFY2019), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Registered Nurses	2.0
Physician Assistant	1.0
Dental Assistant I	3.0
Dental Assistant II	4.0
Office Administration	4.0
Pediatrician	1.0
Housekeeping/maintenance and technical support	1.5
TOTAL	17.5

Source: Table VII.2, page 172.

In Section VII.3, pages 172-173, and Section VII.7, page 176, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 11 contains a copy of a letter from David Kornstein, DDS, expressing his interest in serving 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 165, the applicant provides the proposed staffing for the facility in operating year 2 (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	4.45
TOTAL	9.82

Source: Table VII.2, page 165.

In Section VII.3, page 166, and Section VII.7, page 173, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 30 contains a copy of a letter from Anne Dodds, DDS, expressing her interest in serving as the Clinical Director for the proposed facility. Exhibits 26 and 33 of the application contain 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.

- (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 of Raleigh. In Section II.2, pages 56-57, 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 area hospitals. Exhibit 14 contains copies of letters from the applicant to area hospitals indicating their intention to establish transfer agreements, and a letter from WakeMed to the applicant expressing their interest in establishing a transfer agreement with the applicant. Exhibits 29 and 30 contain letters of support from area dental professionals and other health care providers. 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 28-29, the applicant describes the manner in which it will provide the necessary ancillary and support services. In Section V.2, page 133, the applicant states its intention to establish transfer agreements with WakeMed. Exhibit 15 contains a copy of a letter from WakeMed to the applicant expressing their interest in establishing a transfer agreement with the applicant. Exhibits 26 and 33 of the application contain 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.

- (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 of Raleigh. The applicant proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in 10,542 square feet of leased space in a new office building located at 2209 Century Drive in Raleigh. Exhibit 27 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, pages 181-182 of the application. In Section XI.8, page 196, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the 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. The applicant proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room in 11,688 square feet of leased space in a building located at 958 Vandora Springs Road in Garner. Exhibit 36 contains a letter from an architect that estimates total construction costs at \$2,619,000. In Section VIII.1, pages 178-179, the applicant provides a table showing total construction costs of \$2,352,179, which is \$266,821 lower than the estimate shown in the architect's cost estimate. However, on page 179, line 20 of the table, the applicant includes an additional contingency amount of \$340,927, which is sufficient to fund the difference between the applicant's construction cost estimate and the estimate provided by the applicant's architect. In Section XI.8, page 198, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the 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.

(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 of Raleigh. In Section VI.14, page 166, the applicant projects the following payor mix for the proposed dental ASF in the second operating year (FFY2019):

Payor Category	Projected Cases as Percent of Total
Charity	23.8%
Self-Pay	4.7%
Medicaid	47.1%
Private Insurance	24.4%
Total	100.0%

On page 166, the applicant states, “As its projected utilization is based on specific case volumes from existing users and referrers, documented by letters of support in each case, SCDP of Raleigh has utilized the internal data from the users and referrers that could provide such data in order to estimate the projected age and payor source.” The applicant demonstrated that the medically underserved population 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, page 159, the applicant projects the following payor mix for the proposed dental ASF in the second operating year (FFY2019):

Payor Category	Projected Cases as Percent of Total
Self-Pay/Indigent*	4.2%
Commercial Insurance	6.3%
Medicaid	88.5%
Military	1.1%
Total	100.0%

*In Section III.4, page 98, the applicant states uninsured or self-pay patients are charity care patients pursuant to the facility’s Charity Care Policy in Exhibit 28.

On pages 159-163, the applicant describes its assumptions regarding its payor mix projections, which it states are based on its own historical experience as well as the experience of providers who are expected to refer patients to the dental ASF. The applicant demonstrated that the medically underserved population 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 of Raleigh. In Section VI.9, pages 163-164, the applicant describes the range of means by which a person will have access to the proposed dental ASF. 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 155-156, the applicant describes the range of means by which a person will have access to the proposed dental ASF. 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.

- (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 of Raleigh. In Section V.1, pages 142-145, the applicant states it intends to establish relationships with health professional training programs. Exhibit 22 contains copies of letters from the UNC School of Dentistry and Wake Technical Community College 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 131-132, the applicant states it intends to establish relationships with health professional training programs. Exhibit 29 contains copies of letters from the applicant to area health professional training programs expressing an interest in establishing a training agreement, and Exhibit 33 contains copies letters from the UNC School of Dentistry expressing support for 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.

- (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 1: HSA IV, which includes Wake County. 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 1 service area as HSA IV, which includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties. Providers may serve residents of counties not included in their service area.

SCDP of Raleigh. The applicant proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in Raleigh. In Section III.1, pages 90-98, 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 Raleigh as proposed is needed to enhance the quality of care, access to and value of such surgical services for residents of Region 1 as described in the sections below....

Expertise and training is a fundamental cornerstone of the proposed delivery model at SCDP of Raleigh. As evidenced by the credentialing policy included in Exhibit 18, all professionals practicing at SCDP of Raleigh, 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 Raleigh 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 Raleigh will be able to provide care at a lower cost than hospital-based operating rooms. Further, SCDP of Raleigh will not have hospital-based expenses allocated to surgery services, the only expenses are those generated directly by the services provided by SCDP of Raleigh. 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 the 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 project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates 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. The applicant proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room in Garner. In Section V.7, pages 143-146, 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 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 Raleigh, but the dental ASC 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.”

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 the 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 project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates 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.

- (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 1 (HSA IV) may be approved in this review. Because the two applications in this review collectively propose to two Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects with a total of four operating rooms to be located in Region 1, 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-11075-16, is approved and the other application, submitted by SCDP of Raleigh, is denied.

Geographic Accessibility

The 2016 State Medical Facilities Plan identifies the need for one Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with up to two operating rooms to be located in Region 1 (HSA IV). HSA IV includes Chatham, Durham, Franklin, Granville, Johnston, Lee, Orange, Person, Vance, Wake, and Warren counties.

SCDP of Raleigh proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and six procedure rooms in Raleigh. Valleygate proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and one procedure room in Garner. Thus, the two applicants both propose to locate the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project in Wake County. Therefore, with regard to geographic accessibility to the proposed Dental Single Specialty Ambulatory Surgical Facility Demonstration Project for Region 1, the two proposals are comparable.

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 of Raleigh	1,562	23.8%
Valleygate	127	4.1%

MEDICAID CASES OPERATING YEAR 3	Projected Total Cases Provided to Medicaid Recipients	Projected Percentage of Total Cases Provided to Medicaid Recipients
APPLICANT		
SCDP of Raleigh	3,092	47.1%
Valleygate	2,717	88.5%

Source: SCDP of Raleigh cases by payor category are from Form D, page 204 of the application. Valleygate projected cases by payor category are from Form D, pages 206, 209, and 212 of the application. In Section VI.14, page 160, Valleygate states, "All Self Pay are Charity patients."

As shown in the tables above, SCDP of Raleigh projects the highest number of cases to be provided to Charity Care and Medicaid recipients. Therefore, the application submitted by SCDP of Raleigh is the most effective alternative with regard to access by underserved groups.

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 of Raleigh	Valleygate
Gross Revenue	\$12,864,455	\$3,982,813
Cases	6,564	3,070
Gross Revenue/Case	\$1,960	\$1,297

Source: SCDP of Raleigh projected gross revenues and cases are from Form B, page 201 of the application. Valleygate projected gross revenues are from Form B, page 204, and projected cases are from Section IV.1, page 115 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 of Raleigh	Valleygate
Net Revenue	\$7,550,646	\$3,982,813
Cases	6,564	3,070
Net Revenue/Case	\$1,150	\$714

Source: SCDP of Raleigh projected net revenues and cases are from Form B, page 201 of the application. Valleygate projected net revenues are from Form B, page 204, and projected cases are from Section IV.1, page 115 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 of Raleigh	Valleygate
Total Operating Expenses	\$4,161,841	\$2,023,944
Cases	6,564	3,070
Operating Expense/Case	\$634	\$659

Source: SCDP of Raleigh projected operating expenses and cases are from Form B, page 201 of the application. Valleygate projected operating expenses are from Form B, page 204, and projected cases are from Section IV.1, page 115 of the application.

As shown in the table above, SCDP of Raleigh projects the lowest average operating expense per case in the third operating year. However, Valleygate’s projected operating expense per case of \$659 is only \$25, or approximately 4 percent, higher than SCDP of Raleigh’s projected operating expense per case of \$634. Therefore, the two applications are comparable with regard to projected average operating expense 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 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.

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

- SCDP of Raleigh projects the highest average gross revenue per case in the third operating year. See Comparative Analysis for discussion.
- SCDP of Raleigh projects the highest average net revenue 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-11175-16, 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 1 (HSA IV) and is approved. The approval of the application submitted by SCDP of Raleigh would result in Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects in excess of the need determination for Region 1. Consequently, the application submitted by SCDP of Raleigh is denied.

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

- 1. Valleygate Dental Surgery Center of Raleigh, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Valleygate Dental Surgery Center of Raleigh, LLC shall develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with no more than two operating rooms and one procedure room.**
- 3. Valleygate Dental Surgery Center of Raleigh, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
- 4. Valleygate Dental Surgery Center of Raleigh, 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 applicant 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. Valleygate Dental Surgery Center of Raleigh, 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.**