

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 23, 2016

Findings Date: November 23, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

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COMPETITIVE REVIEW

Project ID #: F-11195-16
Facility: Surgical Center for Dental Professionals of Charlotte
FID #: 160290
County: Mecklenburg
Applicant: Surgical Center for Dental Professionals of Charlotte, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Mecklenburg County pursuant to the demonstration project need determination in the 2016 State Medical Facilities Plan

Project ID #: F-11202-16
Facility: Carolinas Center for Ambulatory Dentistry
FID #: 160292
County: Mecklenburg
Applicant: Carolinas Center for Ambulatory Dentistry, LLC
Project: Develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Mecklenburg County pursuant to the demonstration project need determination in the 2016 State Medical Facilities Plan

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 – Both Applications

The 2016 State Medical Facilities (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility (ASF) Demonstration Project with up to two operating rooms (ORs) to be located in Region 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

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

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

Applicant(s) 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 & 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</i>

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

11	<i>The proposed facility shall demonstrate that it will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation. The performance standards in 10A NCAC 14C.2103 would not be applicable.</i>	Value <i>Performing at least a minimum number of surgical procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.</i>
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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 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Furthermore, the proposal must be consistent with the requirements in Table 6D in the 2016 SMFP, which are identified above.

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

Policy GEN-3: Basic Principles, 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: Energy Efficiency and Sustainability for Health Service Facilities, 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, Certificate of Need 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 is required to submit a plan for 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 Mecklenburg County.

Surgical Center for Dental Professionals of Charlotte, LLC (SCDP of Charlotte) proposes to develop a dental and oral surgery ASF with two operating rooms and two procedure rooms to be located at 100 Judson Avenue in Charlotte (Mecklenburg County).

Need Determination

SCDP of Charlotte’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 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Also, in Section II.1, pages 49-53, the applicant adequately demonstrates how its proposal is consistent with the demonstration project requirements in Table 6D in the 2016 SMFP, as follows:

1. In Section II.1.1, page 49, the application contains a description of the percentage ownership interest in the facility by each oral surgeon and dentist.
2. In Section II.1.1, page 50, the applicant states the proposed facility will provide open access to non-owner and non-employee oral surgeons and dentists.

3. In Section II.1.1, page 50, the applicant states the proposed facility will provide only dental and oral surgical procedures requiring sedation.
4. In Section II.1.1, 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.1.1, page 51, 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.1.1, page 51, the applicant states the proposed facility will provide care to underserved dental patients. In Section VI.14, page 174, the applicant projects that more than three 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 patients.
7. In Section II.1.1, 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), American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), and/or The Joint Commission (TJC), and commits to continued compliance with their respective standards.
8. In Section II.1.1, page 52, 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 and/or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency department coverage with at least one hospital.
9. In Section II.1.1, page 52, 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, page 145, 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 III.1, page 118 and Section IV, page 138, 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 Charlotte addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 59-61, Section III.1, pages 88-90, Section III.4, pages 123-124, 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 90-96, Section III.4, pages 124-127, Section VI, pages 161-177, 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, pages 68-120, and Section III.4, page 127, and referenced exhibits. 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, pages 127-128, and Section XI.8, page 207, 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 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.

Carolinas Center for Ambulatory Dentistry (CCAD) proposes to develop a dental and oral surgery ASF with two operating rooms and two procedure rooms to be located at 2736 Rozzelles Road in Charlotte (Mecklenburg County).

Need Determination

CCAD'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 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Also, in Section III.4, pages 120-123, the applicant adequately demonstrates how its proposal is consistent with the demonstration project requirements in Table 6D in the 2016 SMFP, as follows:

1. In Section I.12, pages 18-19, the application contains a description of the percentage ownership interest in the facility by each oral surgeon, dentist and separate company.
2. In Section III.4, page 120, 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 120, the applicant states the proposed facility will provide only dental and oral surgical procedures requiring sedation.
4. In Section III.4, page 120, 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 121, 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 121, the applicant states the proposed facility will provide care to underserved dental patients. In Section VI.14, page 174, the applicant projects that more than three 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 patients.
7. In Section III.4, page 121, 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 122, 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 and/or maintain hospital staff privileges with at least one hospital and to begin or continue meeting Emergency department coverage with at least one hospital.
9. In Section III.4, page 122, 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 122, the applicant states, "*The applicant agrees to provide information required by this criteria for each of the first three full fiscal years of operation.*" However, in Section VI.14, page 196, the applicant provides a projection for each of the first three full federal fiscal years of operation (FFY 2019-FFF2021) 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 (commercial insurance), (v) self-pay and (vi) payment from other sources.
11. In Section IV.1, page 142, 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

CCAD addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, page 47, Section III.4, page 126, 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, page 125, Section VI, pages 178-196, 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, pages 54-113 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 127, and Section XI.8, page 234, 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 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.

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 2: HSA III which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. However, the limit on the number of Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects with up to two operating rooms to be located in Region 2: HSA III 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 criteria, both applications cannot be approved.

SCDP of Charlotte's application is conforming to the need determination, Policy GEN-3 and Policy Gen-4. CCAD's application is conforming with Policy GEN-3, Policy GEN-4 and to the need determination in the 2016 SMFP. Therefore, both applications are 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 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 2 service area as HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Providers may serve residents of counties not included in their service area.

SCDP of Charlotte proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space in a building to be constructed by a third party developer at 100 Judson Avenue in Charlotte (Mecklenburg County). In Section I.10, pages 6-7, the applicant states SCDP Charlotte will lease the space from Hookie Bones Properties, LLC, and management of the facility will be contracted to Papillion Management, LLC. SCDP of Charlotte 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, as follows: Dr. Uday Reebye, 18 percent; other dentists and oral surgeons, three percent, including those named in Exhibit 4 and the dentists and/or oral surgeons who will serve as dental/medical directors for the proposed facilities once they are developed; non-clinical investors, 1.65%. Thus, the current total commitment of shares to dentists and oral surgeons is 21 percent. Please see the list in Exhibit 4 for the names of dentists and oral surgeons currently known. The remaining 77.35 percent ownership of SCDP

of NC is expected to primarily be comprised of dental professionals, as well as some anesthesiologists, and a few other clinical and non-clinical investors.”

In Section II.1, page 48, the applicant describes the proposed project as follows:

“SCDP of Charlotte proposes to lease 9,868 square feet of space in a building to be developed by a third party developer on one of three potential sites in Charlotte for the development of the proposed dental ASC. The shell of the building will be complete prior to developing this proposed project; as such, SCDP of Charlotte may refer to the building as “existing” in various sections of the application. The 9,868 square feet will consist of shell space only, thereby requiring upfit for use as an ASC. All construction costs associated with the necessary upfit will be incurred by SCDP of Charlotte. ...

The ASC will house two licensed operating rooms, two procedure rooms, an anesthesia workroom and control room, a sterilization room, an X-ray room, dry and wet lab area, and clean and soiled utility and supply, as well as men’s and women’s locker facilities, all within the sterile corridor ...

A nurse station, triage area, and pre-operative and post-operative spaces including a dedicated pediatric post-operative recovery room, which are accessible via the sterile corridor, will support the two operating rooms and two procedure rooms, and are shaded orange on the proposed line drawings (Exhibit 10). Additional spaces for a staff lounge, electrical room, and medical gases are also shaded orange.

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

Patient Origin

In Section III.6, page 129, the applicant provides the projected patient origin for the proposed facility for the first two operating years (FFY2018-2019), as summarized below in the table.

SCDP of CHARLOTTE PROJECTED PATIENT ORIGIN			
County*	Year 1 Projected Patients FFY2018	Year 2 Projected Patients FFY2019	Projected Percent of Total Patients
Mecklenburg	1,671	1,880	65.0%
Union	192	215	7.4%
Gaston	172	194	6.7%
Cabarrus	171	192	6.6%
Iredell	141	159	5.5%
Rowan	109	123	4.2%
Lincoln	66	74	2.6%
Stanly	49	55	1.9%
TOTAL	2,571	2,893	100.0%

Source: Table on page 129. *All counties located in the same HSA (III).

In Section III.6, pages 129-130, with regard to its assumptions for projected patient origin, the applicant states,

“SCDP of Charlotte projected its patient origin based on support from its dental professionals in counties in the region, population data, the proposed location of the facility, and the experience of its dental professional supporters and investors in other areas of the state. Given these factors, SCDP of Charlotte assumes that 65 percent of its patients would originate from Mecklenburg County, the county in which the proposed facility will be located. The remaining 35% was assumed to originate from the remaining counties in Region 2 and patient origin within these counties was estimated based on the population distribution within these counties.”

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b), pages 68-100 of the application, the applicant describes the factors which it states support the need for the proposed project, including:

- Barriers to access for Medicaid patients (page 68).
- The lack of access to operating rooms at hospitals and multispecialty ambulatory surgical facilities by dental professionals (pages 73-81).
- Historical and projected population growth in Region 2 (pages 81-85).
- The dentist shortage and need for dental education opportunities for dental students and continuing education for dentists and oral surgeons that the proposed facility would provide (pages 85-88).
- Historical and estimated use rate per 1,000 population for dental and oral surgery cases requiring sedation, based on the experience of Triangle Implant Center (TIC) (pages 101-109).

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

Projected Utilization

In Section IV.1, page 138, the applicant provides the projected utilization for the ORs and procedure rooms at its proposed facility for the first three years of operation following completion of the project (FFY2018-FFY2020), which is summarized as follows:

SCDP OF CHARLOTTE PROJECTED UTILIZATION PY1 - PY3 FFY2018-FFY2020			
	Year 1 FFY2018	Year 2 FFY2019	Year 3 FFY2020
Operating Room Utilization			
Number of ORs	2	2	2
OR Cases	1,600	1,800	2,000
OR Cases/OR	800	900	1,000
Procedure Room Utilization			
Number of Procedure Rooms	2	2	2
Procedure Room Cases	971	1,093	1,214
Procedures/Procedure Room	485	546	607

Source: Table on page 138 of the application.

Regarding the demonstration project in the 2016 SMFP, Criterion #11 in Table 6D, page 91, states, *“The proposed facility shall demonstrate that it will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation. The performance standards in 10A NCAC 14C.2103 would not be applicable.”* As shown in the table above, the applicant projects the proposed facility will perform 2,000 cases in the two ORs, or 1,000 cases in each operating room, in the third operating year (FFY2020); which exceeds the 900 surgical cases per OR required in Table 6D in the 2016 SMFP.

In Section III.1(b), pages 100-120 and Section IV(d), pages 139-148, the applicant provides its methodology and assumptions for projecting utilization for the proposed dental ASF services.

The applicant’s utilization projections are based on the volume, existing and projected, of dental and oral surgery cases that require sedation in Region 2; as well as the applicant’s expected demand for the proposed services at SCDP of Charlotte. The support letters in Exhibit 28 include estimates by dental professionals of the number of dental procedures for patients requiring sedation that they will perform each month at the proposed dental ASF. In Section III.1(b), pages 114-116, the applicant states,

“Based on conservative estimates of market need for Region 2, SCDP of Charlotte expects to provide 3,214 to 3,255 cases annually by the third project year as shown below and has based its projections on the low estimate of 3,214 cases annually.

SCDP of Charlotte believes several factors support its projected utilization. SCDP of Charlotte’s implied market share assumptions are much less than those of SCDP of Raleigh despite the similarities in geography and location. SCDP of Charlotte has the

support of dental professionals in Region 2 who intend to perform cases at the facility. As demonstrated in the support letters provided in Exhibit 29 [sic] SCDP of Charlotte has the support of 25 dental professionals in total, eight of which intend to perform between 13-45 cases per month or 156 to 540 cases annually at the proposed facility once it is operational. The other 17 dental professionals intend to refer patients to the facility. If each of those 17 dental professionals refers a similar number of patients as those who provided specific volumes, between one and 10 patients per month, this group would constitute another 204 to 2,040 patients annually. [Note: Exhibit 28 contains support letters from providers who intend to refer to SCDP of Charlotte; while Exhibit 29 contains support letters from members of the community.]

In total, the intended users and referrers suggest that between 300 and 2,580 cases would be referred to or performed at SCDP of Charlotte annually, which is 80% of its projected year three volume.”

With regard to the projected allocation of the cases between the ORs and procedure rooms, the applicant projects that 2,000 of the 3,214 total cases will be performed in the two operating rooms and the remaining 1,214 cases will be performed in the two procedure rooms. On pages 117-118, the applicant states,

“... no quantitative volume standard such as might be found in CON rules exists for the procedure rooms. However, based on the experience of SCDP of Charlotte’s owners and managers, it believes that the case times in the procedure rooms will be similar to those in the operating rooms, and, as such, the capacity of the rooms will be similar.

Thus, using 900 cases per year per room, the utilization standard for the operating rooms, as the target for the procedure rooms, and assuming that the operating rooms each perform 1,000 cases in year three, each of the two procedure rooms would perform 607 cases in year three, or 67% percent of 900 cases. If only one procedure room was developed, that room would need to operate above 1,000 procedures, or at 135 percent of 900 cases, which would make scheduling more difficult as well as limit future growth.”

Also, the applicant’s projections include the assumption that utilization will “ramp up” over the first three operating years. On page 118, the applicant states,

“SCDP of Charlotte projects the cases estimated ... to be achieved in the third project year following a ramp-up period. SCDP of Charlotte 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.”

SCDP OF CHARLOTTE PY1-PY3 RAMP-UP PERIOD			
	<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>
<i>% Ramp-Up</i>	80%	90%	100%
<i>Operating Rooms</i>	1,600	1,800	2,000
<i>Procedure Rooms</i>	971	1,093	1,214
<i>Total Facility</i>	2,571	2,893	3,214

The applicant discusses its assumptions regarding referrals, utilization and support from dental professionals in the market on pages 115-116. Exhibit 28 contains letters from 25 dental professionals in the proposed market expressing support for the proposed project, eight of which intend to perform collectively between 13 and 45 cases per month (156 to 540 cases annually) at the proposed facility. The applicant assumes that the remaining 17 professionals who did not provide a referral amount will refer between one and 10 patients per month (204 to 2,040 patients 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 68-137, 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 demonstrates the need to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Region 2: HSA III.

Access

Regarding the demonstration project in the 2016 SMFP, Criterion #6 in Table 6D, page 90 states, *“The proposed facility shall provide care to underserved dental patients. At least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients.”* In Section VI.14, page 174, the applicant projects that 51.5% of patients to be served will be Medicaid recipients and 4.5% will be charity care patients. See Section IV.1(d), pages 139-148 and VI.14, pages 171-176, wherein the applicant provides detailed assumptions regarding the projected payor mix for the proposed dental demonstration project. Furthermore, in Section VI.2, pages 161-162, 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 medically underserved. 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 identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

CCAD proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space in a building to be constructed by a third party developer at 2736 Rozzelles Road in Charlotte (Mecklenburg County). In Section I.10, pages 15-16, the applicant states CCAD will lease the space from Regal Joan, LLC, and management of the facility will be contracted to Carolinas Center for Oral & Facial Surgery. CCAD is a limited liability company whose members include seven dentists and Valleygate Dental Surgery Center of Charlotte, LLC. In Section I.12, page 18, the applicant states,

“The list above includes individuals and organizations who are members of CCAD. Table I.2 includes the individual members of Valleygate, which is a separate company comprised of the dentist owners of the Knowles, Smith & Associates, LLP dental practice in Fayetteville, NC. Table I.2 accurately confirms the current structure; however, the structure of CCAD permits it to accept additional members. The applicant expects other local dentist not affiliated with CCOFS to own 33.0 percent. This ownership will shift from the Valleygate portion listed in Table I.2 ... Many area dentists have expressed interest in becoming members of CCAD. However, as of the date of filing of this application, no official agreements or letters of intent have been signed to guarantee ownership for other local dentists. CCAD expects this process to occur after the project is complete. CCAD will hold the CON; the change in membership interests will not affect the ownership of the CON.”

Each of the seven dentist owners of CCAD own seven to eight percent; while Valleygate currently owns 48 percent of CCAD.

In Section II.1, pages 33-34, the applicant describes the proposed project as follows:

“CCAD will be a licensed ambulatory surgical facility that offers dental and oral surgery procedures to people of all ages and all income levels, who meet facility and payor criteria for care in an outpatient surgical setting. It will serve only patients whose care and recovery will require less than 24 hours of care. Services will include pre-operative screening, pre and post-operative care, surgical support of sedation, and patient and family preventive health education.

A central objective of the project is to improve access to oral surgery and dental sedation procedures that require sedation in a safe, licensed, surgical setting. A particular focus will be patients of pediatric dentists. These patients endure significant obstacles to scheduling care in licensed surgical facilities, including long wait times.

... It will have two operating rooms, two special procedure rooms and a ten-unit pre and post-surgery care area, which will include four private rooms. The applicant will have the entire facility designed specifically for dental and oral surgery cases; its design will accommodate a flexible response to changing care delivery patterns. The four private rooms in the pre- and post-surgery will have flexibility of use for history

and physical examinations prior to admission, as well as for procedures that require conscious sedation, but do not require the full design support of a procedure room or operating room. The dental ASF will provide full time anesthesiology services and all necessary ancillary support for the clinical services proposed. ...”

In addition to the two operating rooms, the applicant proposes to develop two procedure rooms and four treatment rooms (“*dental treatment suites*”). On page 37, the applicant describes the procedure room as follows:

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

On pages 37-38, the applicant describes the three treatment rooms as follows:

“Outside the sterile core operating rooms, the facility will have four rooms that can serve as exam rooms, dental treatment rooms, or additional private recovery rooms. Due to the relatively low volumes expected for dental treatment, the applicant expects to use only one of these rooms as a treatment suite at any given time, while the others serve as exam rooms and recovery rooms.

The dental treatment suite will have the same equipment used in many dental offices. It will accommodate a variety of dental procedures for both adults and children. It will be distinct from the operating rooms. It 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 the treatment 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 four treatment rooms will include tooth extractions, endodontic therapy (root canals), and periodontal treatment. On pages 36-37, the applicant states,

“Patients treated in the treatment room will meet the strict criteria established for a surgical facility by most payers. For example, these rooms may treat patients associated with Post Traumatic Stress Disorder (PTSD), which is common among members of the military. Most payers, including Medicaid and Medicare, have specific guidelines for cases that qualify for reimbursement as an ASC ‘facility.’ The

applicant will bill payers for a 'facility fee' if the surgical procedure meets the criteria.

The other three rooms will serve as exam rooms or additional recovery rooms to support recovery during the peak load part of the day.

Another function of the private rooms will be exam rooms in which an anesthesiologist or other qualified medical professional can conduct history and physician exams, history and physician updates. ...”

In Exhibit 7, the applicant provides the proposed floor plans which outline the space proposed for all service components. In Section II.1, pages 34-41, the applicant describes the types of procedures to be performed, the design of the two ORs, the two procedure rooms, and the four dental treatment suites, the proposed ancillary and support services to be provided and the proposed equipment to be installed.

Patient Origin

In Section III.6, page 130, the applicant provides the projected patient origin for the proposed facility for the first two operating years (FFY2018-FFY2019), as summarized below in the table.

CCAD PROJECTED PATIENT ORIGIN			
County**	Year 1 Projected Patients FFY2018	Year 2 Projected Patients FFY2019	Projected Percent of Total Patients
Mecklenburg	1,512	1,587	51.4%
Union	274	287	9.3%
Gaston	242	254	8.2%
Cabarrus	225	236	7.6%
Rowan	200	210	6.8%
Iredell	166	174	5.7%
Stanly	93	97	3.2%
Lincoln	84	88	2.8%
All Others*	147	154	5.0%
TOTAL	2,943	3,087	100.0%

*Page 132 of application: Estimate for others is based on review of patient origin for existing ASCs in Mecklenburg County, the significant referral reputation of CCOFS surgeons, and the fact the Mecklenburg County also attracts people from outside the area to come visit family while they seek health care in the larger city. **All counties are located in the same HSA (III).

In Section III.6, page 130, 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 center independent practitioners, and the need for dental surgical services within the applicant’s market. The applicant discusses its assumptions on page 131. The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, pages 54-92, the applicant describes the factors which it states support the need for the proposed project, including:

- Clinical need for dental surgery which encompasses advanced dental disease issues and dental disease in children (pages 55-74).
- Barriers to access to dental and oral surgical services such as medical and dental staff credentialing and licensure requirements, statutory and regulatory requirements; including admitting privileges, and third party reimbursement issues (pages 75-85).
- The lack of access and regular availability of operating rooms at area hospitals (pages 81-82, 88-90).
- The need for specialized dental surgical equipment (page 86).
- The need to reduce the incidence of dental-related emergency room visits (page 87).
- The need for dental surgical services for children of low-income families (pages 70-74)
- Shortages in dental health professionals within the proposed service area (pages 91-92).

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

Projected Utilization

In Section IV.1, page 142, the applicant provides the projected utilization for the ORs and procedure rooms at its proposed facility for the first three years of operation following completion of the project (FFY2018-FFY2020), which is summarized as follows:

CCAD PROJECTED UTILIZATION PY1 - PY3 FFY2018-FFY2020			
	Year 1 FFY2018	Year 2 FFY2019	Year 3 FFY2020
Operating Room Utilization			
Number of ORs	2	2	2
OR Cases	1,935	1,934	1,933
OR Cases/OR	967	967	966
Procedure Room Utilization			
Number of Procedure Rooms	2	2	2
Procedure Room Cases	811	947	1,083
Procedures/Procedure Room	405	473	541
Treatment Rooms			
Treatment Room Cases	197	207	217
Number of Treatment Rooms	1	1	1

Source: Table on page 142 of the application.

Regarding the demonstration project in the 2016 SMFP, Criterion #11 in Table 6D, page 91, states, “*The proposed facility shall demonstrate that it will perform at least 900 surgical cases per operating room during the third full federal fiscal year of operation. The performance standards in 10A NCAC 14C.2103 would not be applicable.*” As shown in the above table, the applicant projects the proposed facility will perform 1,933 cases in the two ORs, or 966 cases in each operating room, in the third operating year (FFY2020); which exceeds the 900 surgical cases per OR required in Table 6D in the 2016 SMFP.

In Section III.1(b), pages 93-113, and Section IV.1, pages 141-161, the applicant provides its methodology and assumptions for projecting utilization for the proposed dental ASF services.

Based on the applicant’s experience and 2012-2014 data collected from Knowles, Smith and Associates, LLP (KSA), a dental practice serving southeastern North Carolina, the applicant assumes that 36.3% of Medicaid patients under age nine required a dental procedure under general anesthesia [See table on page 94] in 2012. 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 nine that will receive dental treatment each year from 2014 through 2021 by HSA [See table on page 97]. On page 98, 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 nine who will require dental services [See table on page 98]. Based on data from the Centers for Disease Control, the applicant assumes that the non-Medicaid patient population under age nine will require dental procedures under general anesthesia at approximately half the rate at which Medicaid patients will require them [See table on page 100]. On page 100, the applicant combines the total projected number of Medicaid patients under nine who will require dental services under general anesthesia with the total projected number of non-Medicaid patients under nine who will require dental procedures under general anesthesia for each year from 2014 through 2020 by HSA [see table on page 101]. On page 102, the applicant estimates the percentage of dental surgery cases in operating rooms for patients over the age of nine based on data provided by the Division of Medicaid Assistance (DMA), as shown in the following table.

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 age nine and older.
 b: Provided by NC Division of Medical Assistance

On page 103, the applicant states,

“To estimate the total population in need, divide the total need for patients under nine from Step 7 by one minus the estimated percent dental surgery cases in operating [sic] for individuals nine and over from Step 8.” [The table on page 103 of the application].

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

HSA	2014	2015	2016	2017	2018	2019	2020	2021
<i>I</i>	9,228	9,172	9,117	9,062	9,009	8,956	8,904	8,852
<i>II</i>	13,131	13,066	13,001	12,937	12,873	12,809	12,746	12,684
<i>III</i>	13,914	13,924	13,936	13,947	1960	13,974	13,988	14,004
<i>IV</i>	11,597	11,577	11,558	11,539	11,521	11,504	11,487	11,471
<i>V</i>	9,648	9,579	9,512	9,447	9,382	9,319	9,257	9,196
<i>VI</i>	8,194	8,100	8,007	7,917	7,827	7,740	7,653	7,568
Total	65,711	65,419	63,131	64,849	64,573	64,302	64,035	63,775

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

On page 109, 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 from 2014 through 2021.

County	2014	2015	2016	2017	2018	2019	2020	2021
Mecklenburg	6,975	7,010	7,045	7,079	7,114	7,149	7,185	7,220
Union	1,509	1,522	1,534	1,546	1,559	1,572	1,584	1,597
Gaston	1,362	1,352	1,342	1,332	1,323	1,313	1,303	1,294
Cabarrus	1,258	1,262	1,266	1,270	1,274	1,278	1,282	1,286
Rowan	1,195	1,173	1,150	1,128	1,106	1,085	1,064	1,044
Iredell	882	881	880	879	878	877	876	875
Stanly	376	373	370	367	363	360	357	354
Lincoln	355	352	349	346	343	339	336	333
Total	13,914	13,924	13,936	13,947	13,960	13,974	13,988	14,004

In Section IV.1, pages 143-145, the applicant provides its estimate of referral sources who have expressed interest and support for the project. The applicant estimates that referral sources would refer 4,020 dental surgical cases to the proposed dental ASF annually. See Exhibit 25 for letters from the dentists expected to refer as well the list of expected referrals by provider. The applicant provides the following table on page 144 of the application.

Table IV.2 – Estimated Cases for CCAD Referral Sources	
Dentists	Cases
David Moore, DDS*	648
Carrie Dunlap, DDS	648
Logan Webb, DDS	648
Robert Young, DDS	624
Oscar Mvula, DDS	300
Cordell Scott, DMD	216
Charles Cooke, DDS	192
Marcela Mujica, DMD	192
Trent C. Pierce, DMD	180
Mike Riemels, DDS	120
Kerry Dove, DDS	72
Michael Cantanese, DDS*	36
Scott Goodman, DDS	36
Dennis Swann, DMD*	24
Paul S. Clarke, IV, DMD	12
Robert Herrin, DDS*	12
Brian Tallent, DDS	60
Total	4,020

*Corrected by Project Analyst based on referrals stated in Exhibit 25. **
 Added by Project Analyst from letters included in Exhibit 25.

On page 145, the applicant states that it then forecasts, “... an initial market share of 17.5 percent of the need for dental surgery cases, increasing to 22 percent of the need served in year three of the proposed project.” The applicant summarizes its forecast in the following table, also on page 145.

TABLE IV.3 – CCAD FORECAST PERCENT OF 8-COUNTY NEED FOR DENTAL SURGERY CASES IN ORs SERVED IN THE FIRST THREE FULL FISCAL YEARS			
2017	2018	2019	2020
17.5%	20.0%	21.0%	22.0%

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 as shown in the above table, 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 22 percent of the total dental surgical cases from the proposed market in 2020.

With regard to this market share projection, on page 145, the applicant states,

- “The estimated market share in 2015 that could be served by the dentists (except oral surgeons) proposing to use CCAD was 29 percent) [.]
- Access to scheduled blocks will increase user efficiency, increasing the number of procedures each dentist can perform.

- *Practices that serve the population in need have expressed interest in referring or bringing patients to dentists who practice at the center. See letters in Exhibit 25.*
- *The increase in percent of need met reflects initial response to pent up demand described in Section III, then gradual absorption of more need after the first year.*
- *The percent applies to the 8-counties only, and does not adjust down for the patients who will come from outside the 8-counties.”*

On page 146, the applicant provides a table as shown below, with its projected market shares for the first three operating years applied to its projected number of patients who will require dental services under general anesthesia for its proposed market.

Table IV.4 - Estimated CCAD Dental Cases by Year				
Notes	Metric	FY2018	FY2019	FY2020
a	Need for Dental Surgery Cases in Hospitals and ASCs in the Proposed Service Area	13,960	13,974	13,988
b	Estimated CCAD Percent of Need Served	20%	21.0%	22.0%
c	Projected Dental Surgery Cases Served	2,792	2,935	3,077

Notes: a: From Table III.13; 2017 equals 1/12 of the total 2017 need

b: Assumption from Step 1

c: a*b; 2017 set to 50 cases

On pages 151-152, the applicant states,

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

Assuming that only this group uses the dental treatment rooms, the applicant assumes that 7.05 percent of total cases will use the dental treatment rooms.

*... (8.2% adult dental cases * 80% in treatment rooms = 7.05% of total cases). The remaining adult dental patients will use the operating rooms for dental surgery cases.*

Multiply total projected dental cases from Table IV.9 [page 150] by 7.05 percent to get Total Cases in Treatment rooms.”

On page 152, the applicant provides a table showing its projected number of cases that will be served in two treatment rooms, based on the assumption that 7.05 percent of the total projected cases will be appropriate for those rooms.

TABLE IV.11 – TOTAL CASES IN TREATMENT ROOMS		
FY2018	FY2019	FY2020
197	207	217

With regard to the projected allocation of the cases between the ORs and the procedure rooms, on page 152, the applicant also states,

“... As described in Section II, CCAD will serve the most acute patients only in operating rooms.

...

Patients classified as ASA III or IV and suitable for outpatient surgery will receive treatment in the operating room ‘only’.”

Based on the applicant’s assumptions regarding patient acuity levels, surgical case times and room capacity [See tables on pages 153-157 and 159-161], the applicant projects the distribution of cases among the three room types for the first three operating years in a table on page 158, which is summarized as follows:

TABLE IV.7 - CCAD TOTAL CASES BY ROOM TYPE					
Notes	Metric	Number of Rooms	FY2018	FY2019	FY2020
a	ORs	2	1,935	1,934	1,933
b	Procedure Rooms	2	811	947	1,083
c	Dental Treatment Rooms	1	197	207	217
d	Total Estimated Cases		2,943	3,087	3,232

- a. High Acuity Cases from Step 5 plus remaining assigned OR cases. Table IV.16 row e
- b. Table IV.16 row f
- c. From Step 2
- d. a + b + c

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 dental procedure under general anesthesia, and the total projected number of Medicaid patients under age nine who will require dental services in the proposed market based on DMA estimates and projected population growth in the proposed market. The applicant projects utilization by non-Medicaid patients based on data from the CDC. The applicant’s market share projections are supported by letters in Exhibits 25 and 30-31, from dental professionals and other healthcare providers, respectively, in the proposed market who have expressed support for the proposed project and/or their intention to refer patients to the proposed facility. There were two additional letters, one indicating intent to refer an average of five cases per month and the other indicating general support of the project.

Projected utilization is based on reasonable and adequately supported assumptions.

Based on review of: 1) the information provided by the applicant in Section III, pages 68-137, 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 demonstrates the need to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Region 2: HSA III.

Access

Regarding the demonstration project in the 2016 SMFP, Criterion #6 in Table 6D, page 90 states, *"The proposed facility shall provide care to underserved dental patients. At least 3 percent of the total number of patients served each year shall be charity care patients and at least 30 percent of the total number of patients served each year shall be Medicaid recipients."*

In Section VI.2, pages 178-180, 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 medically underserved. In Section VI.14, page 191, the applicant projects that 79.53 percent of patients to be served will be Medicaid recipients and 3.76 percent will be charity care recipients. Furthermore, in Section VI.2, pages 178-180, 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 medically underserved. 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 identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates 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 Charlotte. In Section III.8, pages 130-134, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain Status Quo** – The applicant states that maintaining status quo is not an effective alternative because it would not meet the need for the provision of dental procedures for patients requiring sedation.
- **Locate the Facility in Another Part of Region 2** – The applicant states that it determined that Charlotte is 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 equitable access to dental procedures requiring sedation to both children and adults.

After considering the above 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.

CCAD. In Section III.8, pages 133-136, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- **Maintain Status Quo** – The applicant states that maintaining 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, *“... many patients that require general anesthesia in an operating room setting and for those patients who are appropriate for outpatient care, a licensed ambulatory surgical facility is the better location.”*
- **Locate the Facility in Another Part of Region 2** – The applicant states that it rejected this alternative because it determined that Charlotte is the best location because, *“It is*

close to the highest concentration of need in Region 2, highly accessible to patients and providers from across the region, and close to hospitals.”

- Select a Different Scope of Service – The applicant states that its proposed scope of service is based on its determination that, *“an overwhelming need exists among children under the age of nine. In addition, special needs adults or patients requiring extensive surgical procedures, and some individuals with extensive co-morbidities, typically performed in a hospital will be candidates for surgery at the proposed CCAD.”*
- Use Patient Restraints – The applicant states that it rejected this alternative because it determined that, *“restraining children can be an emotionally taxing experience for both the child and parent. Using anesthesia is both less emotionally taxing and more clinically effective.”*

After considering the above alternatives, the applicant chose the alternative represented in the application as 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 Charlotte proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space located at 100 Judson Avenue in Charlotte.

Capital and Working Capital Costs

In Section VIII.1, pages 189-191, the applicant states the total capital cost is projected to be as follows:

SCDP OF CHARLOTTE PROJECT CAPITAL COST	
Construction Contract	\$2,428,088
Fixed Equipment	\$560,161
Movable Equipment	\$57,000
Furniture	\$114,000
Architect & Engineering Fees	\$238,000
Financing Costs	\$25,000
Interest During Construction	\$250,000
TOTAL CAPITAL COST	\$3,672,249

Source: Table on pages 189-191 of the application.

In Section IX.1, page 195, the applicant states there will be \$142,242 in start-up expenses and \$454,053 in initial operating expenses, for total required working capital of \$596,295.

Availability of Funds

In Section VIII.4, page 191, the applicant states that the project capital costs will be funded by a loan from PNC Bank. In Section IX.2, page 195, 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 June 8, 2016, from a Vice President at PNC Bank documenting the bank’s intention to fund the capital and working capital cost for the proposed project with “\$5,000,000 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 Charlotte (Form B), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown below in the table.

SCDP OF CHARLOTTE			
	FFY2018	FFY2019	FFY2020
Total Gross Revenue	\$5,038,774	\$5,669,846	\$6,298,958
Total Net Revenue	\$3,376,512	\$3,799,326	\$4,220,940
Net Revenue Per Case	\$1,313	\$1,313	\$1,313
Total Operating Expenses	\$2,962,073	\$2,994,124	\$3,020,669
Net Income	\$414,439	\$805,202	\$1,200,271

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 Criteria (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the project 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 as well as the operating 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.

CCAD proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in leased space located at 2736 Rozzelles Ferry Road in Charlotte.

Capital and Working Capital Costs

In Section VIII.1, pages 211-212, the applicant states the total capital cost is projected to be as follows:

CCAD PROJECT CAPITAL COSTS	
Construction Contract	\$1,587,715
Fixed Equipment	\$633,099
Movable Equipment	\$115,883
Furniture	\$57,693
Architect & Engineering Fees	\$97,200
Other Consultant Fees	\$300,000
Financing Costs	\$27,916
Interest During Construction	\$52,342
Contingency (15%)	\$430,777
TOTAL CAPITAL COST	\$3,302,625

Source: Table on pages 211-212 of the application.

In Section IX.1, page 219, the applicant states there will be \$68,597 in start-up expenses and \$662,069 in initial operating expenses for total required working capital of \$730,666.

Availability of Funds

In Section VIII.4, page 216, the applicant states that First Citizen’s Bank has expressed interest in loaning the funds for the proposed project capital costs. The applicant states that the lessor, Regal Joan, LLC, has agreed to finance the construction of the proposed building shell on the site. In Exhibit 37, the applicant provides a letter dated June 7, 2016, from a Senior Vice President at First Citizen’s Bank documenting the bank’s intention to fund the capital and working capital cost for the proposed project with a loan amount of \$5,000,000. Also, in Exhibit 39, the applicant provides a letter dated June 14, 2016 from the manager of Regal Joan, LLC stating that it would be willing to provide the land and develop and finance a building for the proposed project, “*up to \$5,000,000 in fixed capital for development of the project.*” In addition, the applicant provides a letter from a Senior Vice President at BB&T stating, “*We welcome the opportunity to assist Bob Sweeney and Regal Joan, LLC with this endeavor by financing up to \$3,500,000 of the capital costs of the 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 CCAD (Form B, page 242), the applicant projects that revenues will exceed operating expenses in each of the first three full operating years of the project, as shown below in the table.

CCAD PROJECT CAPITAL COST			
	FFY2018	FFY2019	FFY2020
Total Gross Revenue	\$5,055,723	\$5,294,773	\$5,543,523
Total Net Revenue	\$2,366,193	\$2,811,655	\$2,943,748
Net Revenue Per Case	\$804	\$911	\$911
Total Operating Expenses	\$2,261,573	\$2,411,835	\$2,484,005
Net Income	\$104,620	\$399,820	\$459,743

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 Criteria (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the project 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 as well as the operating 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.

C – Both Applications

The 2016 State Medical Facilities (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility (ASF) Demonstration Project with up to two operating rooms (ORs) to be located in Region 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

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

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

Therefore, the 2016 SMFP defines the Region 2 service area as HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Providers may serve residents of counties not included in their service area.

SCDP of Charlotte proposes to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with two operating rooms and two procedure rooms to be located in Charlotte in Mecklenburg County, which is located in Region 2: HSA III. 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 2 or the state. Therefore, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved dental and oral surgery ASFs. Consequently, the application is conforming to this criterion.

CCAD proposes to develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with two operating rooms and two procedure rooms to be located in Charlotte in Mecklenburg County, which is located in Region 2: HSA III. 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 2 or the state. Therefore, the applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved dental and oral surgery ASFs. 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 Charlotte. In Section VII.2, page 178, the applicant states that it will contract with Papillion Management, LLC, which will employ the staff for the proposed facility. In Section VII.2, page 179, the applicant provides the proposed staffing for the facility in operating year 2 (FFY2019), as shown below in the table.

SCDP OF CHARLOTTE PROPOSED STAFFING	
Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Registered Nurses	1.5
Physician Assistant	0.5
Dental Assistant I	1.5
Dental Assistant II	2.0
Office Administration	2.5
Pediatrician	1.0
Housekeeping/Maintenance/Technical Support	1.5
TOTAL	11.5

Source: Table VII.2, page 179.

In Section VII.3, pages 179-180, and Section VII.7, page 184, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 10 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.

CCAD. In Section VII.2, page 198, the applicant provides the proposed staffing for the facility in operating year 2 (FFY2019), as shown below in the table.

CCAD PROPOSED STAFFING	
Position	Number of Full-Time Equivalent (FTE) Positions
Administrators	2.00
Registered Nurses	2.27
Dental Assistants	1.10
Sterilization Tech	1.10
CRNAs	Contracted
Non-health Professionals/Technical Personnel	5.51
TOTAL	11.98

Source: Table VII.2, page 198.

In Section VII.3, page 199, and Section VII.7, page 205, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 29 contains a copy of a letter from Dale Misiak, DMD, expressing his interest in serving as the Clinical Director for the proposed facility. Exhibit 25 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 Charlotte. In Section II.2, pages 55-56, the applicant describes the manner in which it will provide the necessary ancillary and support services. In Section V.2, page 153, the applicant states its intention to establish transfer agreements with area hospitals. Exhibit 13 contains copies of letters from the applicant to area hospitals indicating its interest to establish transfer agreements. 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.

CCAD. In Section II.2, pages 42-43, the applicant describes the manner in which it will provide the necessary ancillary and support services. In Section V.2, page 164, the applicant states its intention to establish transfer agreements with Carolinas HealthCare System-Carolinas Medical Center-University Hospital (CMC-University). Exhibit 12 contains a copy of an email from Carolinas HealthCare System-University Hospital to the applicant expressing their interest in establishing a transfer agreement with the applicant. Exhibits 25 and 30-31, of the application contain copies of letters from area dental professionals and other health care providers, respectively, 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 Charlotte proposes to develop a dental and oral surgery ambulatory surgery facility with two ORs and two procedure rooms in 9,868 square feet of leased space in a new office building to be constructed at 100 Judson Avenue in Charlotte. 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 189-191 of the application. In Section XI.8, page 207, 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.

CCAD proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in 10,708 square feet of leased space in a building located at 2736 Rozzelles Ferry Road in Charlotte. Exhibit 35 contains a letter from an architect that estimates total construction costs at \$1,587,715. In Section VIII.1, page 211, the applicant provides a table showing total construction costs of \$1,587,715 which matches the estimate shown in the architect's cost estimate. In Section XI.8, page 234, 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 Charlotte. In Section VI.14, page 174, the applicant projects the following payor mix for the proposed dental ASF in the second operating year (FFY2019):

SCDP of CHARLOTTE PROJECTED PAYOR MIX – FFY2019	
Payor Category	Projected Cases as Percent of Total
Charity	4.5%
Self-Pay	12.7%
Medicaid*	51.5%
Private Insurance	31.3%
Total	100.0%

*Includes Health Choice

As shown in the table above, the applicants project that 51.5% of all cases will be covered by Medicaid. However, the applicants state that the Medicaid payor category includes Health Choice. Health Choice is a program for individuals who are under the age of 21 and do not qualify for Medicaid. On page 174 of the application, SDCP states that of the 51.5% Medicaid total, 33.3% is for individuals under the age of 21 and 61.0% is for individuals 21 years old or older. On pages 144-145, the applicant states that included in the Medicaid/Health Choice payor category for OY2 (FY 10/1/2018 – 9/30/2019) there will be 333 patients under 21 and 1,155 patients 21 or older and the total overall number of patients will be 2,893 (999 + 1,894 = 2,893). With the information available, it is not possible to determine how many of the 333 patients under 21 will be Medicaid patients and how many will be Health Choice patients. For purposes of determining a Medicaid percentage, if all 333 patients under 21 are not included, that leaves 1,155 Medicaid patients out of a total of 2,893 patients in OY2, or 39.9% (1,155 / 2,893 = .399 or 39.9%). The applicant demonstrated that medically underserved groups will have adequate access to the proposed services. Moreover, the projected payor mix is consistent with the requirements in Table 6D in the 2016 SMFP. Therefore, the application is conforming to this criterion.

In Section IV(d), pages 139-148, the applicant states its assumptions regarding payor mix for the proposed dental ASF. The applicant demonstrates 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.

CCAD. In Section VI.14, page 191, the applicant projects the following payor mix for the proposed dental ASF in the second operating year (FFY2019):

CCAD PAYOR MIX – FFY2019	
Payor Category	Projected Cases as Percent of Total
Charity Care	3.76%
Self-Pay	1.61%
Medicaid	79.53%
Commercial Insurance	14.59%
Military/TRICARE	.51%
Total	100.00%

On pages 191-196, 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 demonstrates that medically underserved populations 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 Charlotte. In Section VI.9, page 171, 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 patient will access to the proposed services. Therefore, the application is conforming to this criterion.

CCAD. In Section VI.9, pages 186-187, 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 Charlotte. In Section VI.1, pages 149-153, the applicant describes its intention to establish relationships with health professional training programs. Exhibit 22 contains copies of letters from UNC-Chapel Hill, UNC-Charlotte, Central Piedmont Community College, Rowan-Cabarrus Community College, East Carolina, and 3D Dentists (provides training for general dentists and implant surgical specialists) 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.

CCAD. In Section V.1, pages 162-163, the applicant describes its intention to establish relationships with health professional training programs. Exhibit 27 contains copies of letters from the applicant to area health professional training programs expressing an interest in establishing a training agreement, and Exhibit 27 also contains a copy of the letter from the LSU School of Dentistry in New Orleans expressing support for proposed project and their intention to establish a clinical training agreement with the applicant. In addition, Exhibit 27 contains copies of letters from the UNC School of Dentistry and ECU School of Dental Medicine expressing support for proposed project. 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 (SMFP) includes an adjusted need determination for a Dental Single Specialty Ambulatory Surgical Facility (ASF) Demonstration Project with up to two operating rooms (ORs) to be located in Region 2: HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. On pages 90-91, the 2016 SMFP states:

“Dental Single Specialty Ambulatory Surgical Facility Demonstration Project

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

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

Therefore, the 2016 SMFP defines the Region 2 service area as HSA III, which includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties. Providers may serve residents of counties not included in their service area.

SCDP of Charlotte proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Charlotte. In Section III.1, pages 88-100, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The development of SCDP of Charlotte as proposed is needed to enhance the quality of care, access to, and values of such surgical services for the residents of Region 2 as described in the sections below. ...

Expertise and training is a fundamental cornerstone of the proposed delivery model at SCDP of Charlotte. As evidenced by the credentialing policy included in Exhibit 18, all professionals practicing at SCDP of Charlotte, 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 Charlotte 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 Charlotte will be able to provide care at a lower cost than hospital-based operating rooms. Further, SCDP of Charlotte will not have any hospital-based expenses allocated to surgery services; the only expenses are those generated directly by the services provided by SCDP of Charlotte. As a result, patients and payors will not incur the 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.

CCAD proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Charlotte. In Section V.7, pages 173-177, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. On page 173, the applicant states,

“The project will offer competition by providing a new clinical concept. Existing operating rooms will still be able to compete with CCAD, but the dental ASF will require others to compete in both cost and quality. It will create a better option for

dental and oral 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 N.C. Gen. Stat. §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 2 (HSA III) may be approved in this review. Because the two applications in this review collectively propose two Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects with a total of four operating rooms to be located in Region 2, 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 Carolinas Center for Ambulatory Dentistry, LLC, Project I.D. # F-11202-16, is approved and the other application, submitted by Surgical Center for Dental Professionals of Charlotte, 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 2 (HSA III). HSA III includes Mecklenburg, Cabarrus, Gaston, Iredell, Lincoln, Rowan, Stanly and Union counties.

SCDP of Charlotte proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Charlotte. CCAD proposes to develop a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Charlotte. Thus, the two applicants both propose to locate the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project in Charlotte in Mecklenburg County. Therefore, with regard to geographic accessibility to the proposed Dental Single Specialty Ambulatory Surgical Facility Demonstration Project for Region 2, 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 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 access by underserved groups.

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 Charlotte (FFY2020)	145	4.5%
CCAD (CY2020)	122	3.9%

MEDICAID CASES OPERATING YEAR 3	Projected Total Cases Provided to Medicaid Recipients	Projected Percentage of Total Cases Provided to Medicaid Recipients
APPLICANT		
SCDP of Charlotte (FFY2020)	1,655	51.5%
CCAD (CY2020)	2,571	82.2%

Source: SCDP's of Raleigh cases by payor category are from Form D, page 215 of the application. CCAD's projected cases by payor category are from Form D, pages 244, 247, and 250 of the application.

As shown in the tables above, SCDP of Charlotte projects the higher number of cases and higher percentage of cases to be provided to Charity Care recipients and CCAD projects the higher number of cases and higher percentage of cases be provided to Medicaid recipients. SCDP of Charlotte is the more effective alternative with regard to access by Charity Care recipients; while CCAD is the more effective alternative with regard to access by Medicaid recipients.

Projected Average Gross Revenue per Case

The following table shows the projected average gross revenue per case in the third full 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 lower average gross revenue per case is the more effective alternative with regard to this comparative factor.

Third Full Operating Year	SCDP OF CHARLOTTE FFY2020	CCAD CY2020
Gross Revenue	\$6,298,958	\$5,543,523
Cases	3,214	3,232
Average Gross Revenue/Case	\$1,960	\$1,715

Source: SCDP of Charlotte's projected gross revenues and cases are from Form B, page 212 of the application. CCAD's projected gross revenues and projected cases are from Form B, page 242 of the application.

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

Projected Average Net Revenue per Case

The following table shows the projected average net revenue per case in the third full 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 lower average net revenue per case is the more effective alternative with regard to this comparative factor.

Third Full Operating Year	SCDP OF CHARLOTTE FFY2020	CCAD CY2020
Net Revenue	\$3,602,101	\$2,943,748
Cases	3,214	3,232
Average Net Revenue/Case	\$1,120	\$911

Source: SCDP of Charlotte’s projected net revenues and cases are from Form B, page 201 of the application. CCAD’s projected net revenues and projected cases are from Form B, page 242 of the application.

As shown in the table above, CCAD projects the lowest average net revenue per case in the third full operating year. The application submitted by CCAD 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 full 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 lower average operating expense per case is the more effective alternative with regard to this comparative factor.

Third Full Operating Year	SCDP OF CHARLOTTE FFY2020	CCAD CY2020
Total Operating Expenses	\$3,020,669	\$2,484,005
Cases	3,214	3,232
Average Operating Expense/Case	\$940	\$769

Source: SCDP of Charlotte’s projected operating expenses and cases are from Form B, page 212 of the application. CCAD’s projected operating expenses and cases are from Form B, page 242.

As shown in the table above, CCAD projects the lower average operating expense per case in the third operating year. The application submitted by CCAD is the more effective alternative with regard to projected average operating expense per case.

SUMMARY

The following is a summary of the reasons the proposal submitted by Carolinas Center for Ambulatory Dentistry, LLC is determined to be the more effective alternative in this review:

- **CCAD** projects to serve the higher number of Medicaid recipients in the third full operating year. See the Comparative Analysis for discussion.
- **CCAD** projects the lower average gross revenue per case in the third full operating year. See the Comparative Analysis for discussion.
- **CCAD** projects the lower average net revenue per case procedure in the third full operating year. See the Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by Surgical Center for Dental Professionals of Charlotte, LLC is determined to be a less effective alternative in this review than the approved applicant.

- **SCDP of Charlotte** projects to serve a lower number of Medicaid recipients in the third full operating year. See the Comparative Analysis for discussion.
- **SCDP of Charlotte** projects a higher average gross revenue per case in the third full operating year. See the Comparative Analysis for discussion.
- **SCDP of Charlotte** projects a higher average net revenue per case in the third full operating year. See the Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by Carolinas Center for Ambulatory Dentistry, LLC, Project I.D. #F-11202-16, is the more 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 2 (HSA III) and is approved. The approval of the application submitted by Surgical Center for Dental Professionals of Charlotte, LLC would result in Dental Single Specialty Ambulatory Surgical Facility Demonstration Projects in excess of the need determination for Region 2. Consequently, the application submitted by Carolinas Center for Ambulatory Dentistry, LLC is denied.

The application submitted by Carolinas Center for Ambulatory Dentistry, LLC is approved subject to the following conditions.

- 1. Carolinas Center for Ambulatory Dentistry, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Carolinas Center for Ambulatory Dentistry, LLC shall develop a Dental Single Specialty Ambulatory Surgical Facility Demonstration Project with no more than two operating rooms and two procedure rooms.**
- 3. Carolinas Center for Ambulatory Dentistry, 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. Carolinas Center for Ambulatory Dentistry, LLC shall comply with all applicable criteria in Table 6D in the 2016 State Medical Facilities Plan.**
- 5. Carolinas Center for Ambulatory Dentistry, 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.**