REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conforming as Conditioned NC = Nonconforming NA = Not Applicable

Decision Date: Findings Date:	November 4, 2022 November 4, 2022
C	
Project Analyst: Co-Signer:	Ena Lightbourne Mike McKillip
Project ID #:	F-12249-22
Facility:	Valleygate Dental Surgery Center of South Charlotte
FID #:	220578 Maaklanhung
County: Applicant(s):	Mecklenburg Valleygate Dental Surgery Center of Charlotte, LLC
Project:	Develop a new ASF by relocating no more than one OR from Valleygate Dental Surgery Center Charlotte, LLC with two procedure rooms upon project completion

REVIEW CRITERIA

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

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Valleygate Dental Surgery Center of Charlotte, LLC, ("applicant") proposes to develop a new Ambulatory Surgical Facility (ASF) by relocating no more than one operating room (OR) from Valleygate Dental Surgery Center Charlotte ("VDSC Charlotte") with two procedure rooms. The new facility, Valleygate Dental Surgery Center of South Charlotte ("VDSC South") will have a total of one operating room and two procedures room upon project completion.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2022 SMFP applicable to this review. Therefore, Criterion (1) is not applicable this review.

- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

The applicant was approved to develop a dental and oral ASF with two operating rooms pursuant to the 2016 SMFP Dental Single Specialty Ambulatory Surgical Facility Demonstration Project (Project F-11202-16). The demonstration project allowed the certificate of need holder to develop dental OR facilities in different regions across the state to avoid a concentration of dental ORs in one service area. The applicant is proposing to relocate one Dental Single Specialty Ambulatory Surgical Facility operating room from an existing Demonstration Project facility in Region 2. The 2022 SMFP states that Region 2 consist of counties in Health Service Area (HSA) III, Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties.

Patient Origin

In Section C, page 36, the applicant states that the proposal involves the development of a new ASF, therefore, there is no historical patient origin to report. However, the applicant does provide the historical patient origin of VDSC Charlotte, an existing facility in Mecklenburg County.

The following tables illustrate historical and projected patient origin.

Valleygate Dental Surgery Center Charlotte Historical Patient Origin 01/01/2021-12/31/2021 CY2021							
County Patients % of Total							
Mecklenburg	1,962	54.5%					
Gaston	562	15.6%					
Union	267	7.4%					
Cabarrus	199	5.5%					
Lincoln	84	2.3%					
Iredell	64	1.8%					
Rowan	37	1.0%					
Stanly	20	0.6%					
Other (other NC Counties and							
other States	407	11.3%					
Total	3,602	100.0%					

Valleygate Dental Surgery Center South Charlotte Projected Patient Origin								
County		-12/31/2026 2026	01/01/2027	-12/31/2027 2027	01/01/2028-12/31/2028 CY2028			
	Patients	% of Total	Patients	% of Total	Patients	% of Total		
Mecklenburg	1,909	55.4%	1,930	55.4%	1,951	55.4%		
Gaston	366	10.6%	370	10.6%	374	10.6%		
Union	232	6.7%	234	6.7%	237	6.7%		
Cabarrus	13	0.4%	13	0.4%	13	0.4%		
Lincoln	102	3.0%	103	3.0%	104	3.0%		
Iredell	13	0.4%	13	0.4%	13	0.4%		
Rowan	13	0.4%	13	0.4%	13	0.4%		
Stanly	13	0.4%	13	0.4%	13	0.4%		
Lancaster	136	4.0%	138	4.0%	139	4.0%		
York	357	10.4%	361	10.4%	365	10.4%		
In-Migration	292	8.5%	295	8.5%	298	8.5%		
Total	3,446	100.0%	3,484	100.0%	3,522	100.0%		

Source: Section C, page 39

In Exhibit C.3 the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant assumes that the new VDSC South's patient origin will be consistent with VDSC Charlotte's historical patient origin.
- The applicant assumes that some patients will transfer their care to the new VDSC South after the transfer of one operating room from VDSC Charlotte in 2025.

• The applicant used data from the North Carolina Office of State Budget Management (NCOSBM) and the South Carolina Revenue and Fiscal Affairs office to project the number of Medicaid eligibles and the percentage by county in the 10-county service area, which is projected to be VDSC South's primary payor source. (note: Although Region 2 consists of only eight counties, the applicant included Lancaster and York counties in the state of South Carolina to the primary service area based on historical patient origin and the counties' shared border with Mecklenburg County).

Analysis of Need

In Section C, pages 41-63, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The clinical need for dental surgery based on the prevalence of childhood dental disease, such as Early Childhood Caries, which is a communicable disease that can be transferred to others. (pages 41-44)
- The unmet dental needs and the lack of access to dental care among children identified as underserved, which is projected to grow as the population grows. (pages 45-50)
- The benefits of pediatric dental treatment under general anesthesia performed in an ambulatory surgical facility. (pages 51-52)
- The proposed project will provide an alternative to the barriers to dental treatment presented in hospitals. (pages 52-55)
- Advantages of dental treatment in an ambulatory surgical facility (pages 55-59)
- The proposed VDSC South will improve capacity by allowing more patients to be treated more conveniently and promptly which can prevent cases of disease advancement and reduce dental-related emergency room visits. (pages 59-60)
- The proposed VDSC South will provide access to a more cost-effective setting that will increase savings to the NC Medicaid program and increase access for those eligible for Valleygate DSCs' charity program. (page 60)
- Expanding access to pediatric dentists alleviates some of the existing delivery system issues in Region 2. (page 61)
- Local pediatric dentists estimate that the proposed VDSC South could improve access for 3,000 to 3,300 new patients per year. (page 61)
- VDSC South can alleviate some of the access barriers experienced by pediatric dentists as the number of providers grow, which is projected to be faster than the demand for dental services. (pages 62-63)

The information is reasonable and adequately supported based on the following:

The applicant is proposing to develop a new ASF by relocating one operating room from the existing VDSC Charlotte in the service area. The proposal will provide a cost-effective alternative that will meet the clinical need for pediatric dental surgery, address the lack of access to dental services by the underserved, and improve capacity to treat patients with immediate dental needs.

Projected Utilization

VDSC South Projected Utilization							
	Partial Full FY 7/1/25- 12/31/25	1 ^{s⊤} Full FY CY2026	2 ND Full FY CY2027	3 RD Full FY CY2028			
Operating Rooms	-						
Total # ORs	1	1	1	1			
Outpatient Surgical Cases	568	1,149	1,161	1,174			
Outpatient Surgical Case Time	1.2	1.2	1.2	1.2			
Outpatient Surgical Hours	664.6	1,343.8	1,358.6	1,373.6			
Group Assignment	6	6	6	6			
Standard Hours per OR per Year	1,312	1,312	1,312	1,312			
Total Surgical Hours/Standard Hours							
Per OR per Year	0.5	1.0	1.0	1.0			
Procedure Rooms							
Number of Procedure Rooms	2	2	2	2			
Total Number of Procedures	1,136	2,297	2,322	2,348			

In Section Q, page 136, the applicant provides projected utilization, as illustrated in the following table.

In Section Q, pages 140-153, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Determine the estimated population of all Medicaid eligibles in the 10-county primary service area

The applicant used data from the North Carolina Medicaid Division of Health Benefits (NCDMA) and the South Carolina Revenue and Fiscal Affairs Health (SCMcaid) to estimate population of all Medicaid eligibles in the 10-county primary service area. The applicant projected the number of Medicaid eligibles from 2023 through 2028 in the 10-county service area by applying the historical three-year average annual growth rate (2018-2020) of Medicaid eligibles by county. The applicant states that 87 percent of all VDSC Charlotte patients are Medicaid beneficiaries.

Та	able 1-Projec	ted Medicai	d Eligibles b	y County, 20	23-2028	
County	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028
Cabarrus	51,301	53,747	56,309	58,994	61,807	64,754
Gaston	66,615	68,274	69,976	71,719	73,506	75,338
Iredell	41,199	43,271	45,447	47,733	50,134	52,656
Lincoln	18,585	18,942	19,306	19,677	20,056	20,441
Mecklenburg	257,918	258,621	259,327	260,034	260,743	261,454
Rowan	43,275	44,642	46,053	47,508	49,009	50,557
Stanly	15,741	16,030	16,325	16,624	16,930	17,241
Union	42,235	43,544	44,894	46,286	47,721	49,200
Lancaster	24,836	25,617	26,422	27,252	28,109	28,992
York	65,024	66,713	68,447	70,225	72,050	73,922
Total SA ME						
Population	626,726	639,401	652,505	66,054	680,065	694,557

Source: Section Q, page 142

Step 2: Estimate the dental/oral case use rate of Medicaid in 2019

Using data from NCDMA, the applicant divides the total number of claims for outpatients with general anesthesia in an ambulatory surgical setting for 2019 by the total number of Medicaid eligible during same period to determine the number of claims per 1,000 population.

Table 2-Mediciad Eligibles with a Dental Surgery Claims with Anesthesia, 2019	2019
a. Total Medicaid Dental Surgery Patients	38,635
b. Total Medicaid Eligibles	2,076,672
c. Patients with Dental Surgery Claims per 1,000 Population* (Use Rate)	18.6
Source: Section Q, page 143	
*a / b x 1,000	

Step 3: Estimate the number of Medicaid eligible dental/oral surgical cases in the VDSC South 10-county primary service area at the 2019 NC Medicaid dental surgery use rate.

The applicant applied the dental surgery use rate (*Step 2*) to the projected number of Medicaid eligibles (*Step 1*) to project the number of Medical eligible dental surgery cases with anesthesia in the 10-county service area.

Table 3-Estimated Medicaid Eligible Dental Surgery Cases, VDSC South 10-County Primary Service Area, 2023-2028								
	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
Total Medicaid Cases	11,660	11,896	12,139	12,391	12,352	12,922		

Source: Section Q, page 144

Step 4: Estimate the number of total dental surgical cases in the 10-county service area, 2023-2028

To project the total number of dental surgical cases in the 10-county service area, including patients with other payor sources, the applicant divided the projected number of Medicaid eligible dental/oral surgical cases (*Step 3*) by 87 percent, VDSC Charlotte's historical percentage of Medicaid patients. The applicant assumes that the payor mix will be similar to VDSC Charlotte's historical payor mix.

Table 4-Estimated Medicaid Total Eligible Dental Surgery Cases, VDSC South 10-County Primary Service Area, 2023-2028							
CY2023 CY2024 CY2025 CY2026 CY2027 CY2028							
Total Cases	13,402	13,673	13,953	14,243	14,543	14,853	

Source: Section Q, page 144

Step 5: Estimate the number of total dental surgical cases after in-migration, 2023-2028

VDSC Charlotte has historically served patients residing outside of the 10-county service area. The applicant states that 8.5 percent of VDSC Charlotte patients reside outside of the service area. The applicant divided the projected number of dental surgical cases (*Step 4*) by 91.5 percent to project the number of dental surgical cases after in-migration.

Table 5-Estimated Total Eligible Dental Surgery Cases, after In-Migration, 2023-2028							
	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028	
Total Cases	14,644	14,940	15,246	15,563	15,890	16,229	

Source: Section Q, page 145

Step 6: Estimate the number of dental surgical cases appropriate for a freestanding ambulatory Surgery Center compared to a Hospital Outpatient Department (HOPD)

The applicant states that 10 percent of dental surgery procedures are performed in a HOPD. To account for this segment of the patient population, the applicant divided the total dental surgical cases after in-migration (*Step 5*) by 90 percent.

Table 6-Estimated Total Eligible Dental Surgery Cases,								
Appropriate for an ASC, 2023-2028								
	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
Total ASC Cases	13,180	13,446	13,722	14,007	14,301	14,606		

Source: Section Q, page 145

Step 7: Determine average case time for dental surgical cases

The 2022 SMFP does not report case times for any of the Valleygate facilities, however, the applicant used Group 6 Standard Hours per Operating Room per Year and applied the 2022 SMFP Operating Room Standard Methodology.

2019
1,312
70.1
1.2

Step 8: Estimate total dental surgical hours needed in the VDSC South Service area, 2023-2028

The applicant multiplied the projected number of dental surgical cases appropriate for an ASF (*Step 6*) by the average hours per case (*Step 7*).

Table 8-Estimated Total Dental Surgery Hours,								
for an ASC Needed in the VDSC South Service Area, 2023-2028								
CY2023	CY2024	CY2025	CY2026	CY2027	CY2028			
15,398	15,710	16,032	16,365	16,709	17,065			
	ded in the CY2023	ded in the VDSC Sout	ded in the VDSC South Service ACY2023 CY2024 CY2025	ded in the VDSC South Service Area, 2023 CY2023 CY2024 CY2025 CY2026	ded in the VDSC South Service Area, 2023-2028 CY2023 CY2024 CY2025 CY2026 CY2027			

Source: Section Q, page 146

Step 9: Estimate the number of dental only operating rooms necessary to meet the need in the VDSC South Service Area, 2023-2028

The applicant applies the 2022 SMFP Operating Room Standard Methodology to determine the projected need for dental only operating rooms in the service area during 2023-2028 and its impact on the VDSC Charlotte and VDSC South operating and procedure rooms, as illustrated below.

Table 9-Estimated Need for Total Dental only Operating Rooms in the VDSC South Service Area, 2023-2028								
County	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
a. Total Dental Only Surgical								
Hours Needed	15,398	15,710	16,032	16,365	16,709	17,065		
b. Hours Required per OR at								
Group 6 Facility	1,312	1,312	1,312	1,312	1,312	1,312		
c. ORs Needed in ASFs to Meet								
the Dental Surgical Need	11.7	12.0	12.2	12.5	12.7	13.0		
d. Dedicated Dental ORs in the								
Service Area	2.0	2.0	2.0	2.0	2.0	2.0		
e. Dental Only OR								
Surplus/(Deficit)	(9.7)	(10.0)	(10.2)	(10.5)	(10.7)	(11.0)		

Source: Section Q, page 146

a. Total dental surgical hours, Step 8, Table 8

b. Per Step 3e, page 52, 2022 SMFP

c. a / b

d. The only dedicated dental operating rooms in the service area are at VDSC Charlotte.

e. d - c

Table 10-Impact of VDSC Charlotte and VDSC South Dental Only Operating and Procedure								
Room on the Estimated Need in the VDSC South Service Area, 2023-2028								
County	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
a. Total Dental Only Surgical								
Hours Needed	15,398	15,710	16,032	16 <i>,</i> 365	16,709	17,065		
b. Hours Required per OR at								
Group 6 Facility	1,312	1,312	1,312	1,312	1,312	1,312		
c. ORs Needed in ASFs to Meet								
the Dental Surgical Need	11.7	12.0	12.2	12.5	12.7	13.0		
d. Dedicated Dental ORs and PRs								
in the Service Area	4.0	4.0	7.0	2.0	7.0	7.0		
e. Dental Only OR								
Surplus/(Deficit)	(7.7)	(8.0)	(5.2)	(5.5)	(5.7)	(6.0)		

a. Total dental surgical hours, Step 8, Table 8

b. Per Step 3e, page 52, 2022 SMFP

c. a / b

d. VDSC Charlotte and VDSC South total operating and procedure rooms; CY 2025 reflects VDSC South coming online after the relocation. VDSC Charlotte and VDSC South are the only dedicated dental ambulatory surgical facilities in the service area.

e. d - c

Step 10: Determine the VDSC Charlotte dental surgical historical patient growth, 2020-2022

Table 11-VDSC Charlotte Dental Surgical Cases, 2020-2022 (Annualized)									
CY2020 CY2021 CY2022									
	Annualized								
Total Surgical Cases 2,229 3,602 4,108									
Total Surgical Cases	2,229	3,602	4,10						

Source: Section Q, page 149

Step 11: Determine the population growth rate of the primary service area, 2023-2028

The applicant used NCOSBM and SCFAO data to calculate the average annual growth rate in the 10-county service area.

Table 12-Estimated Average Annual Growth Rate of the										
10-County Primary Service Area, 2023-2028										
	CY2023 CY2024 CY2025 CY2026 CY2027 CY2028 AAGR									
Total	Total									
Population 2,831,099 2,881,965 2,931,051 2,980,210 3,031,330 3,084,056 1.7%										

Source: Section Q, page 149; NCOSBM & SCFAO

Step 12: Determine the Valleygate dental surgical cases growth in the primary service area at the primary service area average annual total population increase, 2023-2028

The applicant applied the average annual growth identified in *Step 11* to project the total number of cases available to both VDSC Charlotte and VDSC South.

Table 13-Estimated Number of VDSC Charlotte and VDSC South at Population Growth, 2023-2028							
CY2023 CY2024 CY2025 CY2026 CY2027 CY2028							
a. Estimated Number of Cases	4,179	4,251	4,324	4,399	4,475	4,552	
b. Net Change from 2022	71	143	216	291	367	444	

a. Previous year cases x (1 + average annual population growth rate Step 11)

b. Current year cases – annualized cases 2022

Step 13: Estimate the number of cases performed at VDSC South, 2023-2028

Although VDSC Charlotte and VDSC South are equally accessible, the applicant assumes that half of the population growth cases will shift to VDSC South upon project completion. Additionally, the applicant assumes that cases will shift to VDSC South based on the support of the pediatric dental community, including providers than plan to perform surgeries at both locations.

Table 14-Estimated Number of Dental Surgical Cases at VDSC South, 2023-2028								
	CY2023	CY2024	Partial CY2025	CY2026	CY2027	CY2028		
a. Percent of increase cases to shift	0.0%	0.0%	25.0%	50.0%	50.0%	50.0%		
b. Number of growth cases to VDSC								
South			54	146	184	222		
c. Estimated shifted cases from								
existing PDs			121	241	241	241		
d. Expected new cases from new								
PDs			1,530	3 <i>,</i> 059	3,059	3 <i>,</i> 059		
e. Net cases at VDSC South			1,704	3,446	3,484	3,522		

Source: Section Q, page 151

a. Estimated percent of net change cases that will shift to VDSC South

b. a x net change from 2022, Step 12, Table 13, row b

c. Shifted cases at VDSC South per referrals

d. New cases at VDSC South per referrals

e. b + c + d

Step 14: Estimate the number of cases performed at VDSC Charlotte, 2023-2028

The applicant subtracts the total number of cases expected to shift to VDSC South (*Step 13*) from the projected number of cases identified in *Step 12* to project the number of remaining cases at VDSC Charlotte. The applicant adds the total projected number of cases from both facilities.

Table 15-Estimated Number of Dental Surgical Cases as VDSC Charlotte, 2023-2028								
	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
a. Total Valleygate surgical cases at								
pop growth	4,179	4,251	4,324	4,399	4,475	4,552		
b. Number of growth cases to VDSC			54	146	184	222		
c. Estimated shifted cases from								
existing PDs			175	387	425	463		
d. Cases remaining at VDSC								
Charlotte	4,179	4,251	4,150	4,013	4,051	4,089		

Source: Section Q, page 151

a. Estimated number of total Valleygate cases at population growth, Step 12, Table 12, row a

b. Step 13, Table 14, row b

c. Step 13, Table 14, row c

d. a – b -c

Table 16-Estimated Number of Dental Surgical Cases at VDSC Charlotte, 2023-2028								
Location	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
a. VDSC Charlotte	4,179	4,251	4,150	4,013	4,051	4,089		
b. VDSC South			1,704	3,446	3,484	3,522		
c. Total Valleygate Cases	4,179	4,251	5 <i>,</i> 854	7,458	7,534	7,611		

Source: Section Q, page 152

a. Step 14, Table 15, row d

b. Step 13, Table 14, row e

c. a + b

Step 15: Allocate dental surgical cases to operating and procedure rooms

The proposed project is part of a demonstration project which requires the proposed facility to perform at least 900 surgical cases per year per operating room during the third operating year, as stated in the 2022 SMFP. The applicant states:

"...it is necessary to allocate estimated surgical cases to the operating and procedure rooms at each location to ensure the operating rooms meet the standard."

The applicant's assumptions include the following:

- VDSC South will begin offering services July 1, 2025, operating one operating room and two procedure rooms through the third project year.
- Upon project completion, VDSC Charlotte will convert one operating room to a procedure room and begin operating one operating room and three procedure rooms through the third operating year.
- Surgical cases are scheduled based on room availability not room designation, therefore, estimated surgical cases are distributed equally among all available rooms at VDSC Charlotte and VDSC South.

Table 17-Allocation of Dental Surgical Cases to Operating and Procedure Rooms at								
VDSC Charlotte and VDSC South, 2023-2028								
VDSC Charlotte	CY	CY	Jan-June	Jul-Dec	CY	CY	CY	
VDSC Chanotte	2023	2024	CY2025	CY2025	2026	2027	2028	
a. Total Cases	4,179	4,251	2,075	2,075	4,013	4,051	4,089	
b. Total Rooms	4	4	4	4	4	4	4	
c. Number of Cases per Room	1,045	1,063	519	519	1,003	1,013	1,022	
d. Operating Rooms	2	2	2	1	1	1	1	
e. Total Operating Room Cases	2,089	2,126	1,037	519	1,003	1,013	1,022	
f. Procedure Rooms	2	2	2	3	3	3	3	
g. Total Procedure Room Cases	2,089	2,126	1,037	1,556	3,009	3,038	3,067	
VDSC South								
a. Total Cases				1,704	3,446	3,484	3,522	
b. Total Rooms				3	3	3	3	
c. Number of Cases per Room				568	1,149	1,161	1,174	
d. Operating Rooms				1	1	1	1	
e. Total Operating Room Cases				568	1,149	1,161	1,174	
f. Procedure Rooms				2	2	2	2	
g. Total Procedure Room Cases				1,136	2,297	2,322	2,348	

a. Total cases by year; CY 2023-CY 2028, Step 14, Table 16, Rows a and b

b. Total rooms at the center

c. a / b

d. Total operating rooms: VDSC Charlotte decrease in second half of CY2025 reflects when VDSC South comes online e. c x d

F. Total operating rooms: VDSC Charlotte increase in second half of CY2025 reflects when VDSC South comes online G. c x f

Step 16: Market share of outpatient dental surgical cases, sensitivity test

The applicant projects that VDSC Charlotte and VDSC South will capture 52 percent of the dental surgical cases based on Valleygate DSC's historical experience. VDSC Charlotte and VDSC South will be the only provider in the service area that offers dental-only facilities and has support from pediatric dentists who plan to perform surgeries at both facilities.

Table 18-Reasonable Test of Estimated Valleygate Dental Surgical Cases, 2023-2028								
Location	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028		
a. Estimated Need	13,180	13,446	13,722	14,007	14,301	14,606		
b. Total Valleygate Cases	4,179	4,251	5,854	7,458	7,534	7,611		
c. Market share Outpatient Cases	31.7%	31.6%	42.7%	53.2%	52.7%	52.1%		

Source: Section Q, page 154 a. *Step 6*, Table 6 b. *Step 14*, Table 16, row c

c. b / a

Projected utilization is reasonable and adequately supported based on the following:

• The applicant's projections of total dental surgical cases performed at the proposed VDSC South are supported by the historical growth rates of dental surgical cases

performed at VDSC Charlotte and the projected population growth in the 10-county service area.

- The applicant reasonably projects the number of cases that will shift to VDSC South based on VDSC Charlotte's historical in-migration of patients residing outside of the 10-county service area, projected population growth, the additional access to new pediatric dentists, and the support of the pediatric dental community, including providers than plan to perform surgeries at both locations.
- Projected utilization during the third full fiscal year of operation meets the minimum of 900 surgical cases per year per operating room required by the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project Criteria, as stated in the 2022 SMFP.

Access to Medically Underserved Groups

In Section C, page 69, the applicant states:

"VDSC South will adopt the policies of its management company Valleygate Holdings.

...

Valleygate DSCs accept patients regardless of gender, gender preference, race ethnicity, age, or income, they can and do also serve people who have disabilities.

VDSC South will seek certification by Medicare and Medicaid and will provide services to both sets of beneficiaries. Patients will be able to access care at VDSC South through referrals by dentists."

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	96.1%
Racial and ethnic minorities	80.0%
Women	45.9%
Persons with Disabilities	100.0%
Persons 65 and older	0.0%
Medicare beneficiaries	0.0%
Medicaid recipients	87.1%

Section C, page 71

In Section C, pages 69-71, the applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

С

Although the applicant is proposing to relocate one operating room from VDSC Charlotte, reducing the number of operating rooms from two to one operating room, the applicant will increase its procedure room inventory from two to three procedure rooms. All procedures are performed in either the operating room or procedure room based on availability. On page 76, the applicant states:

"Upon licensure of VDSC South, VDSC Charlotte will reduce its operating room inventory from two to one and increase its procedure room inventory from two to three. This change is only a license designation change. VDSC Charlotte will not reduce any services, staff, or medical equipment as a result of this change. In fact, because all rooms have the exact same design and can accommodate any procedure type, VDSC Charlotte will be able to continue scheduling surgical procedures as it did prior to VDSC South's opening."

The information is reasonable and adequately supported based on the following:

- Although the applicant is proposing to reduce the number of operating rooms, the applicant's proposal includes increasing the number of procedure rooms.
- The applicant's proposal will not result in an interruption to services because all of the facility's rooms can accommodate any procedure type.

Access to Medically Underserved Groups

In Section D, page 77, the applicant states:

"...VDSC Charlotte will continue to serve all of the identified groups...in the same manner after VDSC South opens as it did before.

...

Valleygate DSCs accept patients regardless of gender, gender preference, race, ethnicity, age, or income, it can and does also serve most people who have disabilities."

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use surgical services will be adequately met following completion because the proposed VDSC South will incorporate the existing financial assistance and non-discrimination policies of its management company, VDSC Holdings.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

In Section E, page 82-87, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain Status Quo-The applicant states that this alternative is less effective considering the increased volume at VDSC Charlotte, project growth of Medicaid eligible patients, and the limited accessibility to dental services in area hospitals and ASFs.

Choose a Different Location-The applicant states that the proposed location is the best location based on its accessibility. The location will be in proximity to Mecklenburg County specialty providers and dentists who serve patients in their clinics and ASFs.

Develop More/Less Procedure Rooms-The applicant states that developing the one operating room and less procedure rooms than what is proposed would not add enough capacity to serve the market.

Renovate or Build New-The applicant states that renovating or building a new space would not be a cost-effective alternative.

Expand the Existing Facility-The applicant dismissed this alternative because the existing space is land-locked, and the developer guidelines will not permit expansion.

Wait Until the Agency Declares the Demonstration Project Officially Complete-The applicant states that waiting for the Agency to declare the demonstration project complete can delay the project for almost a year risking an increase in construction and land acquisition costs. Therefore, this alternative is not cost-effective.

Wait for the Standard Methodology to show an Operating Room Need Determination-The applicant states that based on the proposed surplus of operating rooms in Region 2 counties, as stated in the Proposed 2023 SMFP, a need for operating rooms may not be available for several years. Further, if a need is available, more than likely it would be competitive and does not guarantee the applicant would be awarded the Certificate of Need.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant's proposal is the most effective alternative to meet the projected growing demand for operating rooms and enhance accessibility to dentists and specialty providers.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the stated above. Therefore, the application is approved subject to the following conditions:

- 1. Valleygate Dental Surgery Center of Charlotte, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall develop a new Ambulatory Surgical Facility (ASF) by relocating no more than one OR from Valleygate Dental Surgery Center Charlotte with two procedure rooms upon project completion.
- 3. Upon completion of the project, Valleygate Dental Surgery Center of South Charlotte shall be licensed for no more than one operating room and two procedure rooms and Valleygate Dental Surgery Center of Charlotte shall be licensed for no more than one operating room and three procedure rooms.
- 4. **Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on May 1, 2023.
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
- 6. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.
- 7. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 8. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.

- 9. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 10. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
- 11. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

Capital and Working Capital Costs

In Section Q, page 155, the applicant projects the total capital cost of the project, as shown in the table below.

VDSC South						
Capital Costs Construction/Renovation						
Contract(s)	\$1,728,745					
Architecture/Engineering Fees	\$302,712					
Medical Equipment	\$691,069					
Non-Medical Equipment	\$368,947					
Furniture	\$56,147					
Consultant Fees	\$50,000					
Other (Contingency)	\$319,762					
Total	\$3,517,381					

In Section Q, page 156 and Exhibits K.4 and F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit K.4 and Exhibit F.1, the applicant provides a detailed breakdown of the estimated costs for medical and non-medical equipment, furniture, and construction costs.
- Other costs are based on the applicant's experience and an estimated 10% contingency cost.

In Section F, page 90, the applicant projects that start-up costs will be \$234,968 and initial operating expenses will be \$304,722 for a total working capital of \$539,690. On page 178, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up expenses are based on as salaries, utilities, and rental expenses incurred during the first few months during the partial year (July 2025) prior to the first operating year of the project.
- Other working capital expenses are calculated based on monthly net cash inflow/outflow and cumulative cash flowing during the partial year prior to the first three years of the project.

Availability of Funds

In Section F, page 88, the applicant states that the capital cost will be funded, as shown in the table below.

Туре	VDSC South	Total
Loans	\$3,517,381	\$3,517,381
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Total Financing	\$3,517,381	\$3,517,381

Sources of Capital Cost Financing

In Section F, page 91, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$539,690
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$0
Lines of credit	\$0
Bonds	\$0
Total *	\$539,690

Exhibit F.2 contains a letter dated August 15, 2022, from the Senior Vice President of First Citizen's Bank stating their commitment to finance the project. Exhibit F.2 also contains a letter from the Chief Executive Officer of Valleygate Holdings, stating their commitment to use the funds from First Citizen's Bank for the project. On pages 176-177, the applicant provides the loan amortization schedule.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the tables below.

VDSC South	1 st Full FY CY 2026	2 nd Full FY CY 2027	3 rd Full FY CY 2028
Total Operating Room Cases	1,149	1,161	1,174
Total Gross OR Revenues (Charges)	\$6,068,767	\$6,135,648	\$6,203,684
Total Net OR Revenue	\$1,407,624	\$1,423,137	\$1,438,917
Average Net Revenue per OR Case	\$1,225	\$1226	\$1226
Total Operating Expenses (Costs)	\$1,239,820	\$1,250,331	\$1,263,721
Average Net Operating Expenses per OR Case	\$1,079	\$1,077	\$1,076
Net Income	\$467,804	\$172,786	\$175,196
Total Procedure Room (PR) Cases	2,297	2,322	2,348
Total Gross PR Revenues (Charges)	\$12,137,533	\$12,271,296	\$12,407,368
Total Net PR Revenue	\$2,815,248	\$2,846,274	\$2,877,835
Average Net Revenue per PR Cases	\$1,226	\$1,226	\$1,226
Total Operating Expenses (Costs)	\$2,479,639	\$2,500,662	\$2,527,442
Average Net Operating Expenses per OR Case	\$1,080	\$1,077	\$1,076
Net Income	\$335,609	\$345,612	\$350,393

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q, page 164, of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

The applicant was approved to develop a dental and oral ASF with two operating rooms pursuant to the 2016 SMFP Dental Single Specialty Ambulatory Surgical Facility Demonstration Project (Project F-11202-16). The demonstration project allowed the certificate of need holder to develop dental OR facilities in different regions across the state to avoid a concentration of dental ORs in one service area. The applicant is proposing to relocate one Dental Single Specialty Ambulatory Surgical Facility operating room from an existing Demonstration Project facility in Region 2. The 2022 SMFP states that Region 2 consist of counties in Health Service Area (HSA) III, Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties.

In Section G, pages 97-98, the applicant identifies the existing and approved facilities in Region 2 that have operating rooms and provides the utilization of oral surgery/dental cases for FY2021. The applicant identifies a total of 41 facilities.

In Section G, page 99, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating room services in Mecklenburg County. The applicant states:

"Primary persons served will be from a ten-county service area that include the eight counties in dental demonstration project Region 2...This area includes the existing VDSC Charlotte from which one operating room will be relocated to the proposed VDSC South. There are no other freestanding dental single specialty ambulatory surgical facilities in Region 2.

VDSC Charlotte is beginning to reach capacity, and the existing demonstration project ASF has insufficient block time to satisfy the needs of pediatric dentists or the patients they serve. Furthermore, the Applicant demonstrates that the presence of operating rooms and surgical facilities alone are not sufficient to remove barriers to care for the population in need.

...

Because VDSC South will provide increased access to dental-only ambulatory operating rooms, it will serve a specific unmet need and therefore will not duplicate services."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

• The applicant's proposal will result in the only freestanding dental single specialty ambulatory surgical facility in service area, therefore, enhancing access to dental-only ambulatory operating rooms.

- The applicant adequately demonstrates that existing providers in the service are is insufficient to meet the projected need of dental services.
- The applicant adequately demonstrates that the proposed operating room services is needed in addition to the existing or approved operating room services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

In Section Q, page 174, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Desition	VDSC South Projected FTE Staff		
Position	1 st Full FY CY 2026	2nd Full FY CY 2027	3 rd Full FY CY 2028
Registered Nurses (RNs)	3.49	3.53	3.56
Surgery Control	1.16	1.18	1.19
Business Office	2.00	2.00	2.00
TOTAL	6.65	6.70	6.75

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 101-102, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant and its parent company, Valleygate holdings, are established employers that recruit staff through traditional means which will including recruiting staff for VDSC South.
- All VDSC South staff will be required the maintain appropriate credentials and attend continuing education programs as evidence of continued competency.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

Ancillary and Support Services

In Section I, page 104, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 105-106, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 106, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant provides over 15 letters of support from area providers stating their support for the project and their interest in utilizing the proposed facility.
- VDSC South leadership's commitment to utilize its established relationships with agencies that provide "*safety nets*."

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

In Section K, page 110, the applicant states that the project involves constructing 7,866 square feet of new space. Line drawings are provided in Exhibit K.I.

On pages 113-114, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed ASF based on the applicant's representations and supporting documentation.

On page 111, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The project will be developed on land that is currently available for purchase and suitable for development, avoiding costs associated with developing the site.
- The design team (architecture, construction, and design) has experience developing other Valleygate DSCs and plans to incorporate cost-saving features.

On page 112, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant projects that operating costs will support lower charges to the public based on the projected market share and conservative use rates.
- The project will provide dental services in an ASF as a more cost-effective option as opposed to offering dental services at a hospital where patients can incur other charges.

On page 112, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

• Application

• Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated 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 ... persons [with disabilities], 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;

С

The applicant is proposing to develop a new facility, therefore, there is no historical payor mix to report. However, the applicant provides the payor mix for a facility owned by the applicant and located in the same service area as the proposed facility.

VDSC Charlotte Historical Payor Mix Last full FY, CY 2021	
Payor Source	Percent of Total
Self-Pay	1.2%
Charity Care	9.0%
Medicaid*	87.1%
Insurance*	2.3%
TRICARE	0.4%
Total	100.0%

Source: Section L, page 117

*Including any manages care plans.

In Section L, page 118, the applicant provides the following comparison.

VDSC Charlotte	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	45.9%	51.5%
Male	54.1%	48.5%
Unknown	0.0%	0.0%
64 and Younger	100.0%	82.2%
65 and Older	0.0%	17.8%
American Indian	0.0%	2.2%
Asian	0.0%	6.2%
Black or African-American	35.0%	24.8%
Native Hawaiian or Pacific		
Islander	0.0%	1.8%
White or Caucasian	20.0%	54.9%
Other Race**	45.0%	10.1%
Declined / Unavailable	0.0%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <u>https://www.census.gov/quickfacts/fact/table/US/PST045218</u>.

**Includes American Indian, Asian, Native Hawaiian or Pacific islander, Hispanic/Latinx, and other races.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

(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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

С

Is Section L, page 119, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 119, the applicant states:

"For information purposes, VDSC Charlotte notes that it met or exceeded all medically underserved requirements in Table 6E of the SMFP, as is demonstrated in annual reports on the file with the NC DHSR Healthcare Planning Section."

In Section L, page 119, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(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

С

In Section L, page 120, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

VDSC South Projected Payor Mix Third full FY, CY 2028	
Payor Source	Percent of Total
Self-Pay	1.2%
Charity Care	9.0%
Medicaid*	87.1%
Insurance*	2.3%
TRICARE	0.4%
Total	100.0%

*Including any manages care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.2% of total services will be provided to self-pay patients, 9.0% to charity care patients, and 87.1% to Medicaid patients.

On page 120, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported. The applicant is proposing to provide dental and oral surgical services as the only service component which is the same service component provided by VDSC Charlotte. The applicant projects payor mix based on the VDSC Charlotte's historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(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.

С

In Section L, page 122, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

In Section M, page 123, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

• Valleygate DSCs has established relationships with schools and training programs which will include the proposed VDSC South.

• The applicant provides documentation of Valleygate Holdings' existing training agreements with several education institutions.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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.

С

The applicant proposes to develop a new ASF by relocating no more than one OR with two procedure rooms upon project completion.

The applicant was approved to develop a dental and oral ASF with two operating rooms pursuant to the 2016 SMFP Dental Single Specialty Ambulatory Surgical Facility Demonstration Project (Project F-11202-16). The demonstration project allowed the certificate of need holder to develop dental OR facilities in different regions across the state to avoid a concentration of dental ORs in one service area. The applicant is proposing to relocate one Dental Single Specialty Ambulatory Surgical Facility operating room from an existing Demonstration Project facility in Region 2. The 2022 SMFP states that Region 2 consist of counties in Health Service Area (HSA) III, Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties.

In Section G, pages 97-98, the applicant identifies the existing and approved facilities in Region 2 that have operating rooms and provides the utilization of oral surgery/dental cases for FY2021. The applicant identifies a total of 41 facilities.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 125, the applicant states:

"As an experienced provider of dental-only surgical services, Valleygate Holdings is expecting to enhance competition by augmenting the services it currently offers at VDSC Charlotte, and promoting improved patient access to Valleygates Holdings' quality, costeffective, and accessible ASF."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 126, the applicant states:

"Because many healthcare insurances policies, including Medicare Part B, cover both hospitals and licensed surgical centers, and require coinsurance for outpatient procedures to be paid out-of-pocket by the patient, the ambulatory surgical centers are less expensive for patients. This applies to self-pay patients and private pay dental policyholders. For these patients, surgeries in the dental single specialty dental ambulatory surgical facility will be significantly less costly to both the payer and to the patient than a hospital-based alternative."

See also Sections C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 127, the applicant states:

"Protocols and processes at VDSC South will match the needs of its patients better than general acute care hospitals or multi-specialty ambulatory surgical facilities...Valleygate DSCs have a specific focus on dental procedures, especially for children, and therefore offer unique features to enhance quality and patient satisfaction; VDSC South will follow this example."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 128, the applicant states:

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

...

As noted elsewhere, facility fees will be lower than for the same procedure in a hospital. Charity care levels meet or exceed the required criteria in the [sic] 2022 SMFP and Valleygate Holdings has relationships with clinics that serve low income and Medicaid at risk patients, thus enhancing access."

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (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.

С

In Section O, page 175, the applicant identifies the ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina.

In Section O, page 131, the applicant states that, during the 18 months immediately preceding the submittal of the application, the Division of Health Service Regulation has not determined any situations resulting in a finding of immediate jeopardy had occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (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

The applicant does not propose to increase the number of operating rooms in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.