

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: June 3, 2021

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: M-12020-21

Facility: Valleygate Dental Surgery Center of Fayetteville

FID #: 160152

County: Cumberland

Applicant(s): Valleygate Dental Surgery Center of Fayetteville, LLC

Project: Add ENT surgery which is a change of scope for Project ID #M-011176-16
(develop a new ASF)

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 Fayetteville, LLC (hereinafter referred to as “Valleygate” or “the applicant”) was approved in Project ID #M-11176-16 to develop a Dental Single Specialty Ambulatory Surgical Center in Fayetteville pursuant to a Dental Demonstration Project in the 2016 State Medical Facilities Plan (SMFP), to provide dental and oral surgical procedures. The 2021 State Medical Facilities Plan (SMFP) amended Table 6D originally published in the 2016 SMFP, to include otolaryngology (ENT) surgical services at the approved Dental Single Specialty Ambulatory Surgical Facility Demonstration Project facilities. This application proposes a change of scope (COS) to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2021 SMFP
- acquire any medical equipment for which there is a need determination in the 2021 SMFP
- offer a new institutional health service for which there are any policies in the 2021 SMFP

Therefore, Criterion (1) is not applicable to 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- (2) Repealed effective July 1, 1987.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.

C

Valleygate proposes a COS to a previously approved project, Project ID #M-11176-16 to develop a Dental Single Specialty Ambulatory Surgical Center in Fayetteville pursuant to a Dental Demonstration Project in the 2016 SMFP, to provide dental and oral surgical procedures. Specifically, the applicant proposes to add otolaryngology (ENT) surgical services to the scope of services currently offered at Valleygate. In Section C.8, page 34, the applicant states:

“With the proposed change, patients who also need ENT surgery would be able to have both dental and ENT surgery in one sitting. The specialist surgeon would work with the dentist or oral surgeon and complete the repair during a single operating room case. This would minimize the amount of anesthesia delivered to the patient, the number of trips to a surgery setting, and lessen the time for a full recovery to six weeks.”

Patient Origin

The 2016 SMFP specifically defined the service areas for the Dental Demonstration Projects into four regions. Valleygate was approved to provide services in the Region 3 service area, defined as HSAs V and VI, which includes Anson, Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Edgecombe, Gates, Greene, Halifax, Harnett, Hertford, Hoke, Hyde, Jones, Lenoir, Martin, Montgomery, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Richmond, Robeson, Sampson, Scotland, Tyrell, Washington, Wayne and Wilson counties.

In Section C, page 35, the applicant states the service area will not change as a result of the addition of ENT surgical services. In Project ID #M-11176-16 the applicant adequately

identified the projected patient origin and no changes are proposed in this application which would affect that determination.

Analysis of Need

In Section C.8, page 34, the applicant explains why it believes the population projected to utilize the proposed ENT surgical services included in the COS application needs the proposed services. The applicant states that approximately 10% of its dental surgery patients require skills from other surgical specialties, particularly otolaryngology (“ENT”). The applicant states that specialist surgeons typically work with dentists and/or oral surgeons in other settings, but the patients it serves must go elsewhere for the ENT services when they are necessary. The applicant states:

“Today, in an abundance of caution, the Valleygate permits only dentists/oral surgeons to participate in cases. Thus, patients with ENT issues caused by underlying dental problems must receive ENT treatment elsewhere. Regardless of specialty or procedure, this means excess travel disruptions for families/caregivers, longer patient recovery periods, inefficient and expensive care. When you consider time for full recovery, on average, the current arrangement disrupts patient life for up to three months.

With the proposed change, patients who also need ENT surgery would be able to have both dental and ENT surgery in one sitting. The specialist surgeon would work with the dentist or oral surgeon and complete the repair during a single operating room case. This would minimize the amount of anesthesia delivered to the patient, the number of trips to a surgery setting, and lessen the time for a full recovery to six weeks.”

The information provided by the applicant is reasonable and adequately supported for the following reasons:

- The applicant’s assumptions are based on its historical experience at its Fayetteville location.
- The applicant bases its stated need for adding ENT services based on need in its service area for ENT services for the patients it serves.
- The applicant provides letters of support for the addition of ENT services in Exhibit I.3.

Projected Utilization

In Section Q, the applicant provides projected utilization as illustrated in the following table:

Valleygate Dental Surgery Center Projected Utilization

| | 1ST FULL FY CY 2022 | 2ND FULL FY CY 2023 | 3RD FULL FY CY 2024 |
|---|---|---|---|
| # Ambulatory ORs | 2 | 2 | 2 |
| Total # ORs | 2 | 2 | 2 |
| Adjusted Planning Inventory | 2 | 2 | 2 |
| # Outpatient Surgical Cases | 1,951 | 2,146 | 2,360 |
| Case Times | 3.1 | 3.1 | 3.1 |
| Total Surgical Hours* | 6,047 | 6,651 | 7,316 |
| Group Assignment | 6 | 6 | 6 |
| Standard Hours per OR per Year | 1,312 | 1,312 | 1,312 |
| Total Surgical Hours/Standard Hours per OR per Year | 4.6 | 5.1 | 5.6 |

*Total surgical hours represents total outpatient data, since Valleygate provides only outpatient surgical services.

In Section Q, page 98a, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

- The applicant projected future cases based on a 10% increase per year from CY 2020 through the third project year (CY 2024). The applicant acknowledged an anomalous decrease in cases during 2020 as a result of the COVID-19 pandemic and the Governor’s ordered closure of ambulatory surgical facilities. The applicant states that in 2019 Valleygate performed 2,095 cases and in 2020 they performed 1,612 cases.
- The applicant examined data from the years 2019 through 2021 (prior to submission of the application), excluding the COVID-19 shut down. The applicant states the data indicates a steady 10% increase, which supports projected increase in utilization by 10% going forward.
- The applicant multiplied 2020 surgical cases by 1.1 (10%) to project future utilization, as shown in the following table:

| | INTERIM PARTIAL FY | 1ST FULL FY | 2ND FULL FY | 3RD FULL FY |
|-------|-----------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 2/13/2021-12/31/2021 | CY 2022 | CY 2023 | CY 2024 |
| Cases | 1,773 | 1,951 | 2,146 | 2,360 |

Source: application page 98a

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

- The applicant relies on its own historical experience in providing dental surgical procedures.
- The applicant explains how the historical data could project utilization at the proposed facility.
- The applicant’s projections for the first FY (CY 2022) are less than its historical experience prior to the anomalous COVID-19 decreased utilization.

Access to Medically Underserved Groups

In Project I.D. #M-11176-16, the Agency determined the applicant had adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

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 application for Project I.D. #M-11176-16 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination. The applicant proposes to serve the same population area and includes those patients who need additional ENT services in addition to oral surgery/dental services.
- Projected utilization following the addition of ENT services is reasonable and adequately supported.
- The application for Project I.D. #M-11176-16 adequately identified the extent to which all residents, including underserved groups, were likely to have access to the proposed services, and there are no changes proposed in this application which would affect that determination.

- (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.

NA

In Project I.D. #M-11176-16, Criterion (3a) was not applicable to that review. There are no changes proposed in this application which would affect that determination. Therefore, Criterion (3a) is not applicable to this review.

- (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.

CA

This application proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

In Section E, page 42, the applicant states there are no alternatives other than the alternative proposed in this application to meet the need. The applicant states:

“The status quo is not a suitable alternative because it is more costly and less effective for patient quality of life. Currently, Valleygate patients requiring ENT work get their ENT care in a hospital setting, which is much more expensive. ... The proposed project is far more effective, and involves completing care in a single trip to the operating room. Moreover, the proposed project will reduce the total anesthesia bill and total patient exposure to anesthesia. Patients will have a single recovery and complete the entire case in a freestanding surgery center.”

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 provides credible 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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Valleygate Dental Surgery Center of Fayetteville, LLC (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. #M-11176-16. Where representations conflict, the certificate holder shall materially comply with the last made representation.**

- 2. The total combined capital expenditure for both projects is \$4,941,030, an increase of \$99,834 over the capital expenditure of \$4,841,196 previously approved in Project I.D. #M-11176-16.**
 - 3. 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.**
 - 4. The certificate holder shall not acquire as part of this project any equipment that is not included in this project's and Project I.D. #M-11176-16's combined proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 5. 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.**
 - 6. 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.

This application proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

Capital and Working Capital Costs

A certificate of need was issued on March 6, 2017 for Project I.D. #M-11176-16 and authorized a capital cost of \$4,841,196. The current application proposes a capital cost increase of \$99,834 over the previously approved capital cost for a total combined capital cost of \$4,941,030 which is approximately 2% over the previously approved capital cost. This application proposes a change of scope and not a cost overrun. The additional capital cost for this project is the cost of medical equipment such as microscopes and stretchers, as shown in the following table from Section Q, page 112a:

Capital Cost Project ID #M-12020-21

| MEDICAL EQUIPMENT | QUANTITY | PRICE PER UNIT | TOTAL COST |
|--------------------------|-----------------|-----------------------|-------------------|
| Microscopes | 4 | \$5,000 | \$20,000 |
| Stretchers | 2 | \$3,500 | \$7,000 |
| Instrument Sets ENT | 4 | \$4,000 | \$16,000 |
| ENT Treatment Cabinets | 2 | \$8,000 | \$16,000 |
| Shipping – 2% | | | \$1,180 |
| Taxes – 7.5% | | | \$4,425 |
| Consultant Fees | | | \$20,000 |
| Contingency | | | \$15,229 |
| Total | | | \$99,834 |

In Section Q the applicant provides the assumptions used to project the proposed increase in capital cost. The applicant adequately demonstrates that the proposed increase in the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains the need for the different costs that make up the combined total increase in capital cost for this COS application and the explanations are reasonable and adequately supported.

In Section F.5, page 49, the applicant states there is no change to the working capital of the project, and that the project is ongoing and operational with current positive cash flow sufficient to cover the minimum staffing and equipment increase associated with this COS application. 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:

- The applicant had previously demonstrated to the Agency in Project I.D. #M-11176-16 that the projected working capital costs in that application were based on reasonable

and adequately supported assumptions, and there are no changes proposed in this application which would affect that determination.

- The applicant adequately explains there will be no increase in working capital costs for this COS application and the explanations are reasonable and adequately supported.

Availability of Funds

In Project I.D. #M-11176-16, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$4,841,196. The current application proposes a capital cost increase of \$99,834 over the previously approved capital cost for a combined total capital cost of \$4,941,030, which is approximately 2% over the previously approved capital cost.

In Exhibit F-5 the applicant provides a February 15, 2020 letter from the Chief Executive Officer for Valleygate that confirms the availability of up to \$115,000 in Operating Reserve Funds for the project. The letter also commits the funds to the project.

The applicant adequately demonstrates the availability of sufficient funds for the proposed increase in the projected capital cost based on the following:

- The applicant provides a letter from an appropriate company officer confirming the availability of the funding proposed for the capital needs of the project and a commitment to use that funding accordingly.
- The applicant commits the funds it proposes to use to fund the capital needs of the project.

Financial Feasibility

In Project I.D. #M-11176-16, the applicant projected revenues would exceed operating expenses during each of the first three full fiscal years of operation following project completion.

In Form F.2b, the applicant projects that revenues will exceed operating expenses in all three project years following completion of the project, as shown in the table below:

| | 1 st Full Fiscal Year | 2 nd Full Fiscal Year | 3 rd Full Fiscal Year |
|---|----------------------------------|----------------------------------|----------------------------------|
| Total Surgical Cases | 1,951 | 2,146 | 2,360 |
| Total Gross Revenues (Charges) | \$16,945,827 | \$18,640,410 | \$20,504,451 |
| Total Net Revenue | \$4,279,831 | \$4,707,814 | \$5,178,595 |
| Average Net Revenue per Surgical Case | \$2,193.66 | \$2,193.76 | \$2,194.32 |
| Total Operating Expenses (Costs) | \$2,957,205 | \$3,059,002 | \$3,194,118 |
| Average Operating Expense per Surgical Case | \$1,515.74 | \$1,425.44 | \$1,353.44 |
| Net Income | \$1,322,626 | \$1,648,812 | \$1,984,477 |

Source: Form C.3b, Form F.2b

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 114a. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for the addition of ENT surgical cases in its updated Pro Forma forms.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 increased 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 increased capital costs 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 costs and charges.

- (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

The applicant proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

In Section G.3, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ENT surgical services in Region 3. The applicant states the proposed addition of ENT services to the existing services would increase

case times, but not long enough to require additional facility capacity. On page 51, the applicant states:

“The proposed change would not increase the number of operating rooms or procedure rooms in these facilities. The cases would be a little longer, but not long enough to require additional facility capacity.”

The proposed change would not cause a major exodus from existing providers.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed ENT services are needed at Valleygate.

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 stated 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.

C

The applicant proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

In Section H, page 54, the applicant states the proposed addition of ENT services to existing services would slightly increase case times. In order to accommodate the increase, the applicant proposes to add Full Time Equivalent (FTE) registered nurse positions over the course of the first three project years (PY), as shown in the following table:

| POSITION | CURRENT FTE STAFF | 1 ST PY (CY 2022) | 2 ND PY (CY 2023) | 3 RD PY (CY 2024) |
|------------------------|----------------------|---------------------------------|---------------------------------|---------------------------------|
| Registered Nurse | 3 | 4 | 4 | 5 |
| Anesthesiologist | 1 | 1 | 1 | 1 |
| Surgical Technician | 1 | 1 | 1 | 1 |
| Central Sterile Supply | 1 | 1 | 1 | 1 |
| Business Office | 1 | 1 | 1 | 1 |
| Clerical | 2 | 2 | 2 | 2 |
| Total | 9 | 10 | 10 | 11 |

Source: application Section Q page 120

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section H, page 54, the applicant describes the methods to be used to recruit or fill new positions and its proposed 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 adequately documents the number of FTEs it projects will be needed to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3 in Section Q.
- The applicant provides adequate documentation of its proposed recruitment, training, and continuing education programs.

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 reasons stated 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.

The applicant proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

In Project I.D. #M-11176-16, the Agency determined the applicant had adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and proposes no changes to those services in this application.

In Project ID #M-11176-16, the Agency determined the applicant adequately demonstrated that the proposed dental and oral surgery services would be coordinated with the existing health care system. In this application, the applicant adequately demonstrates that the proposed ENT surgical services will be coordinated with the existing health care system based on letters of support in Exhibit I.3 and copies of testimony provided during the State Health Coordinating Council hearings held in 2020.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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.

NA

In Section K, page 60 the applicant states the facility is operational and no additional renovation or construction is proposed. The applicant does not propose to:

- construct any new space
- construct more than minimal new space
- renovate any existing space

Therefore, Criterion (12) is not applicable to this review.

- (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 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;

NA

In Project I.D. #M-11176-16, the Agency determined that this criterion was not applicable since the facility did not exist. The current application form does not request 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 for COS or cost overrun applications. Therefore, this criterion is not applicable to this review.

- (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;

NA

In Project I.D. #M-11176-16, the Agency determined that this criterion was not applicable. The applicant proposes no changes in the current application which would affect that determination. Therefore, this criterion is not applicable to this review.

- (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

In Section L, page 66, the applicants project the following payor mix for the entire facility and proposed ENT services during the third full fiscal year, calendar year (CY) 2024 of operation following completion of the project, as shown in the table below:

**Valleygate Dental Surgery Center
 Projected Payor Source CY 2024**

| PAYOR SOURCE | % OF TOTAL PTS SERVED |
|--------------|-----------------------|
| Self-Pay | 0.66% |
| Medicare | 0.00% |
| Medicaid* | 79.28% |
| Insurance* | 5.10% |
| TRICARE | 14.96% |
| Total | 100.00% |

*The applicant states this includes managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.66% of total services will be provided to private pay patients, 14.96% to TRICARE and 79.28% to Medicaid patients.

In Section L, page 67 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 because it is based on the historical payor mix adjusted for future expectations following the addition of ENT services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

In Project I.D. #M-11176-16, the Agency determined the applicant had adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

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.

- (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

In Project I.D. #M-11176-16, the Agency determined the applicant had adequately demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

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.

C

The applicant proposes a change of scope (COS) to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP.

Regarding the expected effects of the proposal on competition in the service area, In Section N.3, page 71 the applicant states:

“Changes will enhance the capacity of Valleygate Dental Surgery center to compete to serve high risk children. ... Under current conditions, children whose dental disease involves ear, nose and throat tissues must either arrange for surgery in two locations ... or arrange for care in a surgical facility that offers both specialties. To minimize patient risk, particularly for children who have Downs Syndrome, the referring physician will choose the one-surgery approach. In most cases, this means scheduling in a hospital. With the two-surgery approach, children must heal from the first surgery before initiating the second.

With the change, Valleygate can compete and offer the full service, accommodating these patients with a single surgery appointment that involves only one fee.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 72, the applicant states the project has a positive impact on cost effectiveness because the patients will be able to

schedule a single surgical case at one time with a single anesthesia charge that will be billed at freestanding ambulatory surgery rates. A single surgery and recovery will allow patients to avoid in-patient hospital charges and reduced follow-up costs.

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

Regarding the impact of the proposal on quality, in Section O, page 73, the applicant states it will continue to operate in compliance with all applicable Federal, State and local laws, regulations or codes and will continue to comply with all material representations of its certificate of need awarded pursuant to Project ID #M-11176-16.

See also Section C of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 72, the applicant states:

“Persons at high risk for the combined surgeries are children in low-income households and/or households with a culture of poor nutritional habits. The proposed change will enable Valleygate to serve more of such individuals at the dental surgery center.”

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 for all the reasons stated 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.

C

In Section Q, Form O, page 122, 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 74, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. According to the files in the Acute 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 occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute 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 proposes a COS to Project ID# M-11176-16 consistent with the amendment in the 2021 SMFP and proposes to add ENT surgical services to the scope of services currently offered at Valleygate. That project approved the development of a dental and oral surgery ambulatory surgery facility with two operating rooms and two procedure rooms in Cumberland County pursuant to the demonstration project in the 2016 SMFP. There are no administrative rules that are applicable to proposals to add ENT services.