

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2021

Findings Date: September 27, 2021

Project Analyst: Mike McKillip

Co-Signer: Fatimah Wilson

Project ID #: J-12087-21

Facility: UNC REX Holly Springs Hospital

FID #: 070823

County: Wake

Applicant: Rex Hospital, Inc.

Project: Develop a 2nd dedicated C-Section OR which is a change in scope for Project ID# J-8669-11 (develop a separately licensed 50-bed hospital)

REVIEW CRITERIA

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

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

NA

Rex Hospital, Inc. (hereinafter referred to as “the applicant”) proposes a change of scope (COS) for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2021 SMFP, nor 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- (2) Repealed effective July 1, 1987.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

The applicant proposes a change of scope (COS) for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section C.8, page 34, the applicant describes the project as follows:

“The proposed project is a change of scope to Project ID # J-8669-11, which was originally approved as the development of a new separately licensed hospital in Holly Springs with no more than 50 licensed general acute care beds, three licensed shared ORs, and one dedicated C-Section operating room. Since the original Certificate of Need (CON) was issued, UNC REX requested several modifications from the Healthcare Planning and Certificate of Need Section (the Agency), which were determined to be in material compliance with the CON on January 11, 2019. As part of the material compliance request, UNC REX asked for approval to develop a second dedicated C-Section operating room; however, this portion of the request was not approved. The Agency stated that a CON would be needed to add a second C-Section room. Thus, the sole change proposed in this project is the addition of a second dedicated C-Section operating room. [Underline in original]. The proposed dedicated

C-Section operating room will be co-located with the approved dedicated C-Section operating room on Floor 3 of the hospital, adjacent to the obstetrics unit.”

Patient Origin

On page 49, the 2021 SMFP states, “An OR’s service area is the single or multicounty grouping shown in Figure 6.1.” In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately identified the population to be served by the proposed project at that time. The applicant proposes no changes in the current application which would change the projected patient origin from the previous project, or which would otherwise affect the Agency’s determination in that project.

Analysis of Need

In Section C.8, pages 34-37, the applicant states the need for the additional dedicated C-section operating room is based on the need to have the operating room for emergency standby capacity. The applicant states,

“The need for the proposed second C-Section room is based on qualitative, not quantitative factors. UNC REX believes that two C-Section rooms are needed to ensure optimal patient safety and quality of care at the approved hospital. Specifically, UNC REX will follow the recommendations from the American College of Obstetricians and Gynecologists (ACOG), as noted in the most recent edition of Guidelines for Perinatal Care, which suggest that while a 30-minute “decision-to-incision” time for emergency C-Sections has been the general consensus among providers historically, some conditions may warrant even shorter intervals necessitating the short-term availability of a sterile operating room for the procedure. As such, UNC REX will maintain this standard by holding an operating room open (unscheduled) any time a C-Section is scheduled in the already approved C-Section room to ensure that an operating room is available for emergency cases. Since the approved hospital will have only three operating rooms which are expected to be well-utilized, UNC REX believes that the most effective approach is to develop a second dedicated C-Section room that can remain unscheduled when the other C-Section room is scheduled, allowing the second room to be on standby in the event an emergency arises. Thus, the need to develop a second dedicated C-Section room is not driven by the expected utilization of the room, but by the need to mitigate the risk of a lack of timely surgical availability for emergency cases. Although the proposed labor and delivery services at UNC REX will involve mostly lower risk patients, the potential for fetal distress or other complications still exists and must be considered in the development of the proposed project. Thus, the proposed development of the second C-Section room is driven by UNC REX’s dedication to patient safety and is reflective of its commitment to achieving optimal outcomes for women and their newborn children. As noted in the response below, the proposed project will not require a cost overrun to the already approved project.

The space for the proposed additional dedicated C-Section operating room will require only minor upgrades, including the necessary gasses and electrical connections, as well as some minor equipment, such as booms and lights required for the surgical cases. Given the ability to develop the project within the CON approved budget without requiring a cost overrun, or without additional construction apart from minor renovations, the proposed project presents a reasonable and effective method of maintaining the standard of care provided currently at UNC REX Hospital and ensuring optimal safety for obstetrics patients at UNC REX Holly Springs Hospital.

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

- The applicant adequately explains the reasons the additional dedicated C-section operating rooms is necessary as part of the new hospital.
- The applicant provides supporting documentation for its statements in Section C.8, pages 34-37.
- The applicant does not propose to change the scope of services offered, other than the addition of a second C-section operating room, or to change the patients projected to be served by the proposed project.

Projected Utilization

In Project I.D. # J-8669-11, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. On page 38, the applicant states,

“As noted above, the proposed project is not based on any expected change in utilization, nor is the proposed development of a second C-Section operating room expected to impact utilization. While either of the C-Section rooms may be scheduled for a case, the other room will be kept unscheduled and available for an emergency case any time one room has a scheduled C-Section. As such, UNC REX does not anticipate the two rooms to be used simultaneously, except in case of an emergency, and thus, the proposed project will not increase the capacity of scheduled C-Section cases or projected C-Section utilization.”

Therefore, the applicant proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency’s determination in that project.

Access

In Project I.D. # J-8669-11, 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. # J-8669-11 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination.
- The applicant adequately explains why the additional dedicated C-section operation room is necessary to provide the population to be served with the services proposed in this application.
- Projected utilization was deemed reasonable and adequately supported in Project I.D. # J-8669-11 and there are no changes proposed in this application which would affect that determination.
- The application for Project I.D. # J-8669-11 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

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. 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

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care

beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section E, page 44, the applicant states there are no alternatives other than the alternative proposed in this application to meet the need. The applicant states,

“As described in Section C.8, the need for the proposed project is to ensure the availability of an appropriate surgical setting in case an emergency arises requiring an immediate C-Section while the one approved dedicated C-Section operating room is occupied. The Agency previously determined that the development of a second dedicated C-Section operating room would not be in material compliance with the conditions of the original application and would thus require a Certificate of Need. As such, there is no other alternative for developing timely surgical availability for emergency C-Section cases in an appropriate operating room setting than the proposed project.”

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 does not propose to change the scope services, other than the addition of a second C-section operating room, or patients to be served from the previously approved Project I.D. # J-8669-11.
- 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. Rex Hospital, Inc. (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. # J-8669-11. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. Upon completion of this project and Project I.D. # J-8669-11, UNC REX Hospital shall be licensed for no more than 32 operating rooms, including no more than 24 shared operating rooms and 3 dedicated C-section operating rooms on the UNC REX Hospital main campus, and no more than three shared operating rooms and two dedicated C-section operating rooms on the UNC REX Holly Springs Hospital campus.**
- 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 March 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**
- 4. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations or a comparable accreditation authority within two years following licensure of the facility.**
- 5. 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 this 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.**

6. **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.**
 7. **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.**
 8. **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.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

Capital and Working Capital Costs

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. In Section F.5, page 51, the applicant states the proposed project does not require a cost overrun, and that no additional working capital will be required for the proposed project. In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the availability of the capital and working capital necessary to develop the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

Financial Feasibility

The applicant provided pro forma financial statements for the dedicated C-section operating rooms 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 table below.

	1st Full FY SFY2023	2nd Full FY SFY2024	3rd Full FY SFY2025
Total Patients	190	257	261
Total Gross Revenues (Charges)	\$3,473,782	\$4,839,710	\$5,054,603
Total Net Revenue	\$2,004,500	\$2,792,691	\$2,916,692
Average Net Revenue per Patient Day	\$10,550	\$10,867	\$11,175
Total Operating Expenses (Costs)	\$1,669,335	\$1,939,377	\$2,009,710
Average Operating Expense per Patient Day	\$8,786	\$7,546	\$7,700
Net Income	\$335,165	\$853,314	\$906,982

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- 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 because the applicant demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal was 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 change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes

to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

On page 49, the 2021 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrate that the project would not result in unnecessary duplication of existing or approved services in the service 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 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 change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services through the first three full fiscal years of operation, as summarized below:

POSITION	FTE Positions SFY2023	FTE Positions SFY2024	FTE Positions SFY2025
Patient Services Manager	0.37	0.37	0.37
Supervisor Clinical Nurse IV LDOR	0.73	0.73	0.73
Clinical Nurse III LDOR	0.99	0.99	0.99
Clinical Nurse II LDOR	4.58	4.58	4.58
Surgical Technician	3.84	3.84	3.84
Health Unit Coordinator	1.54	1.54	1.54
Total	12.00	12.00	12.00

Source: Section Q, Form H

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.3, which is found in Section Q. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, page 55, and in Section Q, Form H, as described above.

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.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Project I.D. # J-8669-11, 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 adequately demonstrated the proposed services would be coordinated with the

existing healthcare system. 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 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. 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.

C

The applicant proposes a change of scope for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

In Section K.5, page 61, the applicant states that the project involves renovation of 520 square feet of space. Line drawings are provided in Exhibit K.5.

In Section K.5, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on page 61.

In Section K.5, 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 information and representations made by the applicant on page 62 of the application.

In Section K.5, page 62, 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 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;

C

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated 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. 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 stated above.

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

C

In Project I.D. # J-8669-11, the Agency determined the application was conforming to this criterion. 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.

- (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 Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the elderly and the medically underserved groups identified in this subdivision would be served by the applicant's proposed services and the extent to which each of these groups would be expected to utilize the proposed 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.

- (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. # J-8669-11, 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. # J-8669-11, 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 for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds.

A certificate of need was issued on January 22, 2014 for Project I.D. # J-8669-11 for an authorized capital cost of \$171,616,236. On January 11, 2019, the applicant received a material compliance determination from the Agency for proposed changes to the project, including construction of a 7-story facility on a smaller footprint rather than a 3-story structure, increasing the general medical/surgical beds from 38 to 44, increasing the number of intensive care beds from four to six, developing 7 labor-delivery-recovery (LDR) beds rather than 8 labor-delivery-recovery-postpartum (LDRP) beds, increasing the unlicensed observation beds from five to ten, increasing emergency department treatment bays from 10 to 24, licensing the hospital under the UNC REX Hospital license rather than licensing it separately, changes to the floor plan, and other minor changes.

This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two.

On page 49, the 2021 SMFP states, “*An OR’s service area is the single or multicounty grouping shown in Figure 6.1.*” In Figure 6.1, page 55 of the 2021 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-8669-11, the Agency determined the applicant had adequately demonstrated the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition would have a positive impact upon the cost effectiveness, quality, and access to the services proposed. 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 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, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified 12 hospitals.

In Section O.4, pages 72-73, the applicant states that during the 18 months immediately preceding the submittal of the application, there were incidents related to quality of care at two facilities: UNC REX Hospital and Onslow Memorial Hospital.

On October 6, 2020, UNC REX Hospital received notification that CMS determined, based on a survey visit completed by DHSR surveyors on October 17, 2019 that UNC REX Hospital was not in compliance with requirements of Responsibilities of Medicare Participating Hospitals in Emergency Cases based on 42 CFR 489.24 (Special Responsibilities of Medicare Hospitals in Emergency Cases). Further, the October 6, 2020 letter indicated that UNC REX Hospital was subject to termination of its provider agreement if compliance was not demonstrated by October 16, 2020. UNC REX Hospital timely submitted a plan of correction on October 13, 2020, which was subsequently accepted on October 21, 2020 as documented in the CMS correspondence letter dated October 21, 2020, which is included in Exhibit O.4. A follow-up desk review was completed, at which time it was determined that actions had been taken to correct the deficiency that was cited, and that procedural changes had been made giving reasonable assurance that a similar violation will not recur and the termination action was withdrawn as documented in the CMS correspondence letter dated October 21, 2020, which is included in Exhibit O.4.

On November 30, 2020, Onslow Memorial Hospital received notification that CMS determined, based on a survey visit completed by the North Carolina Division of Health Service Regulation (DHSR) surveyors on October 13 and 14, 2020 that a potential violation pertaining to the Federal Emergency Medical Treatment and Labor Act (EMTALA) was identified. Further, the letter indicated that Onslow Memorial Hospital was subject to termination of its provider agreement if compliance was not demonstrated by December 23, 2020. Onslow Memorial Hospital timely submitted a plan of correction on December 9, 2020, which was subsequently accepted on December 14, 2020 as documented in the CMS correspondence letter dated December 14, 2020, which is included in Exhibit O.4. A follow-up review was completed by DHSR on December 21, 2020 and information gathered during the survey was forwarded to CMS as documented in the DHSR correspondence letter dated December 23, 2020, which is included in Exhibit O.4.

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, there were no incidents related to quality of care that occurred in any of the applicant's other 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 the hospitals, 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 for Project I.D. # J-8669-11. That project approved the development of a new, separately licensed hospital in Holly Springs with 50 acute care beds, three shared operating rooms, one dedicated C-section operating room and five unlicensed observation beds. This COS application is necessary because the applicant proposes to increase the number of dedicated C-section operating rooms at the new hospital from one to two. There are no administrative rules that are applicable to proposals to add a dedicated C-section operating room.