Comments Regarding UNC REX Holly Springs Hospital C-Section Room Change of Scope CON Application Project No. J-12087-21

Submitted by WakeMed Health & Hospitals August 2, 2021

WakeMed appreciates the opportunity to provide the following comments opposing the certificate of need application filed by Rex Hospital ("UNC REX") to develop an additional C-Section room at UNC REX Holly Springs Hospital.

Overview

In Project No. 12087-21, UNC REX is requesting a Change of Scope to Project No. J-8669-11, to add an additional C-Section room for a total of two C-Section rooms at UNC REX Holly Springs Hospital. UNC REX admits in their application that the justification for this request is merely "qualitative" and is unsupported by any quantitative metrics. This proposed change of scope should not be approved as it is unsupported by relevant data, as well as previous Agency precedent, and has failed to show a reasonable present need.

Previous Agency Precedent

Previous Agency precedent dictates that facilities which cannot demonstrate that the number of C-Sections projected could not be performed in an existing operating room shall not be approved a dedicated C-Section room.

In Project No. J-7843-07, WakeMed proposed two dedicated C-Section rooms to support development of acute care beds and an Obstetric program proposed at WakeMed North Hospital. The Agency denied the request on the basis that WakeMed had not yet demonstrated sufficiently high C-Section utilization and required that WakeMed "not construct space for or develop any dedicated C-Section operating rooms at WakeMed North", despite the projection of 327 C-Sections in Project Year 3. Please see Exhibit 1 for pages excerpted from the Agency Findings for Project No. J-7843.07. The CON Section eventually conditionally approved development of one C-section room at WakeMed North. The Agency has already disregarded that precedent by granting UNC REX Holly Springs one C-Section room, despite their original CON application projecting only 257 C-Sections, 70 fewer cases than WakeMed North projected in Year 3 in Project No. J-7843-07, when it initially denied <u>any</u> C-Section rooms just three years prior.

WakeMed appreciates the Agency's consistency and fairness and supports upholding longstanding precedent which requires applicants to demonstrate the need for additional capacity before additional capacity is approved.

Unreasonable Data Utilized

The sole project component in UNC REX's application is the addition of a second C-Section room; however, the data provided is unrelated and does not include projections for deliveries or obstetric cases. On Application page 34 UNC REX admits that this application is based on "qualitative" factors and is unsupported by any quantitative metrics, thus rendering it non-conforming with Review Criterion 3.

Instead, UNC REX focuses on the utilization of their three operating rooms originally approved in Project No. J-8669-11, which does not translate to a quantifiable need for an additional C-Section room. The operating room data cited includes a number of specialties, <u>except</u> C-Sections, which they note were calculated separately, but were not included anywhere in the application. UNC REX Holly Springs now projects to perform 3,049 inpatient and outpatient surgical cases in three shared operating rooms in its Project Year 3. These projections do not support the development of an additional dedicated C-Section room, as shared operating room utilization is not a predictor of C-Section demand.

UNC REX attempts to compare the new Holly Springs hospital with Rex Hospital, a tertiary acute care hospital with historically high utilization. The comparison between UNC REX Holly Springs and UNC REX Hospital is dubious, as these facilities are not analogous. When compared to a more appropriately sized facility these projections are unreliably overstated. As WakeMed North, a similar facility, reported in its 2019 LRA, a total of 2,871 cases in shared operating rooms and 255 C-Sections performed in one C-Section room, without any C-Sections needing to be performed in a shared operating room. UNC REX does not present any relevant data which would necessitate an additional C-Section room and is therefore non-conforming.

No Reasonable Present Need

UNC REX Holly Springs has not yet opened and therefore cannot show historical need for a second C-Section room. Floor plans included in Exhibit 2 indicate the proposed C-Section room will be located in current "LDR Support Space," which is identical in size and dimension to the planned C-Section room. With UNC REX Holly Springs' floor plans indicating planned future space for an additional C-Section room, it would be prudent to allow for the facility to open and show actual utilization to demonstrate need for a second room.

UNC REX Holly Springs maintains that the request for a second C-Section room is to ensure that one room is left unscheduled to accommodate emergent cases at the time of a previously scheduled C-Section. However, UNC REX Holly Springs projects only 255 C-Sections in Project Year 3. With projections of less than one C-Section per day, their already approved C-Section room will not be fully utilized. In the very rare situations that an emergent C-Section is required at the time of a previously scheduled C-Section, UNC REX Holly Springs has access to three shared operating rooms to accommodate the case.

The UNC REX Holly Springs application cites UNC REX Hospital as justification for a second C-Section room. However, it is stated that UNC REX Hospital performs approximately 1,500 Cesarean deliveries per year in three C-Section rooms, or 500 cases per room annually. In contrast, UNC REX Holly Springs only projects 255 cases in one room, approximately half the utilization of UNC REX Hospital. In the past five years WakeMed North has successfully and safely performed 1,643 C-Sections with optimal outcomes and using only one C-Section room. Of those total C-Sections, 404 cases were reported in the 2021 LRA and all were performed in WakeMed North's one C-Section room.

Additionally, as UNC REX Holly Springs has yet to open, it is unclear if the projections calculated in the application will become reality. Approval of a second C-Section room would be especially premature.

Without utilization to support any of the claims made by UNC REX Holly Springs, it is unnecessary and unreasonable to approve this application solely based on "qualitative" justification which can be abridged down to convenience.

Summary

The UNC REX Holly Springs application did not provide any reasonable or reliable data to quantifiably support the request for an additional C-Section room, as is required to be found conforming by the application process. The inclusion of projected shared operating room volume does not justify a need for a C-Section room, nor does it negate the requirement to provide relevant data. Additionally, Agency precedent set in 2007 would dictate that the facility open and show a quantifiable need prior to the approval of additional C-Section room capacity. WakeMed supports the application process and precedent set by the Agency as the foundation of CON, and requests that this application be denied.

Exhibit 1: Excerpt from Agency Findings – Project #J-7843-07 – Page 18-19

"As shown in the above table, during FFY 2006, only 3.4 cases per operating room per day were performed in the four existing dedicated outpatient operating rooms at WakeMed North Healthplex. The applicants did not demonstrate that the small number of C-sections projected to be performed at WakeMed North Healthplex (327 in Year Three) could not be performed in one of the four existing operating rooms already located on that campus. Thus, the applicants did not demonstrate the need to develop additional operating rooms dedicated for C-sections as opposed to relocating existing operating rooms or using the existing operating rooms at WakeMed North Healthplex.

In summary, the applicants adequately identify the population to be served and adequately demonstrate the need to relocate 20 existing acute care beds from WakeMed Raleigh Campus to WakeMed North Healthplex and to develop 10 new Level I unlicensed bassinets there. However, the applicants did not adequately demonstrate the need to develop six new LDRs or two new dedicated C-section operating rooms at WakeMed North Healthplex. Therefore, the application is conforming to this criterion subject to the following conditions.

- 1. WakeMed (lessee) and WakeMed Property Services (lessor) shall not construct space for or develop any more than four unlicensed labor/delivery/recovery rooms at WakeMed North Healthplex as part of this project.
- 2. WakeMed (lessee) and WakeMed Property Services (lessor) shall not construct space for or develop any dedicated C-section operating rooms at WakeMed North Healthplex as part of this project."

Exhibit 2: UNC Holly Springs Floor Plan



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