COMPETITIVE COMMENTS ON

2022 WAKE COUNTY ACUTE CARE BED & OR NEED DETERMINATIONS

SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

OCTOBER 3, 2022

Six applicants submitted CON applications in response to the need identified in the 2022 SMFP for two (2) additional ORs in Wake County: CON Project ID# J-12252-22 Oakview, ASC, CON Project ID# J-12253-22 Triangle Vascular Care, CON Project ID# J-12260-22 Rex Hospital, CON Project ID# J-12261-22-21 Duke Health Green Level ASC, CON Project ID# J-12248-22 KM Surgery Center, and CON Project ID# J-12264-22 WakeMed Garner Hospital.

Four applicants submitted CON applications in response to the need identified in the 2022 SMFP for 45 additional acute care beds in Wake County: CON Project ID# J-12258-22 Rex Hospital, CON Project ID# J-12259-22 UNC Rex Holly Springs Hospital, CON Project ID# J-12263-22 Duke Raleigh Hospital, and CON Project ID# J-12264-22 WakeMed Garner Hospital.

Based on previous batch reviews that included acute care beds and ORs during the same review cycle, DUHS anticipates the Wake County competitive review for acute care beds and ORs will similarly be combined into one set of Agency Findings. Therefore, this document includes separate comparative reviews for acute care beds and ORs, respectively, along with an independent analysis of each competing application against applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C.

These comments are submitted by DUHS in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the applications, including a comparative analysis and a discussion of some of the most significant issues identified regarding the applicants' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Patient
- Projected Average Total Operating Cost per Patient

Other comparative factors may be utilized based on the facts of the competitive review. The following summarizes the competing applications relative to the potential comparative factors.

Conformity to CON Review Criteria

Four CON applications have been submitted seeking to develop acute care beds in Wake County. The applicants each propose to develop 40 acute care beds. Based on the 2022 SMFP's need determination, only 45 acute care beds can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by DUHS demonstrate conformity to all Criteria:

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
Rex Hospital	J-12258-22	No
UNC Rex Holly Springs Hospital	J-12259-22	No
Duke Raleigh Hospital	J-12263-22	Yes
WakeMed Garner Hospital	J-12264-22	No

The DRAH application is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the DRAH application is the most effective alternative regarding conformity with applicable review Criteria.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

Two applications involve long-standing, existing acute care hospitals which provide numerous types of medical services, i.e., DRAH and UNC Rex. Both DRAH and UNC Rex provide a broader scope of services compared to UNC Rex Holly Springs Hospital and WakeMed Garner.

UNC Rex Holly Springs Hospital has been operational less than one year.[1] In fact, as of August 15, 2022 UNC Rex Holly Springs Hospital has yet to open six of its approved acute care beds.[2] According to UNC Rex Holly Springs Hospital's website, the only specialties offered at the hospital include general surgery and orthopaedics. https://www.rexhealth.com/rh/hospitals-locations/profile/rex-holly-springs-hospital/

WakeMed proposes to develop a new 31-bed acute care hospital in Garner. WakeMed states the services at WakeMed Garner will exclude specialized cardiac and cardiovascular surgery patients, neurosurgery, OB, neonatal, complex oncology, behavioral health, substance abuse, inpatient rehabilitation, trauma, and burn.

For these reasons, DRAH and UNC Rex are more effective alternatives regarding scope of services and UNC Rex Holly Springs Hospital and WakeMed Garner are less effective alternatives.

Geographic Accessibility

There are currently 1,388 existing and approved acute care beds, allocated between three existing health systems in the Wake County Service Area, as illustrated in the following table.

City	Hospital	System	Total Acute Care Bed Inventory*
Raleigh	Duke Raleigh Hospital	DUHS	186 - 40 = 146
	UNC Rex	UNC	418
	WakeMed	WakeMed	610
	Raleigh Total		**1,174**
Cary	WakeMed Cary Hospital	WakeMed	200
	Duke Green Level Hospital	DUHS	40
	Cary Total		**240**
Total Wake County			**1,414**

The following table summarizes the average population per existing and approved acute care beds in the Wake County Municipalities involved in this competitive review.

[1] UNC REX Hospital Holly Springs began serving patients on November 1, 2021. See page 33, J-12259-22.
[2] J-12259-22, Section Q, page 4

Municipality	Existing/Approved Beds	2021 Population	Population/Bed
Raleigh	1,174	470,566	401
Garner	0	32,393	N/A
Holly Springs	50	43,274	865

WakeMed Garner proposes to develop nine acute care beds in Garner, which does not currently host any acute care beds. UNC Rex Holly Springs Hospital proposes to develop nine new acute care beds in Holly Springs. As set forth below, these applications are not conforming with the applicable criteria and cannot be effective alternatives in this review. However, even if the WakeMed Garner and UNC REX Holly Springs applications were otherwise conforming with all criteria and approved, 27 acute care beds could be approved to be developed in Raleigh.

Both DRAH and UNC Rex propose to develop acute care beds in Raleigh. DRAH's proposed project effectively increases access to acute care services in Wake County. DUHS can immediately develop the proposed additional acute care beds because the project does not require renovation or construction. DRAH's proposed additional acute care bed would become operational by July 1, 2023, and the first project year will be FY2024. The 2022 SMFP acute care bed methodology forecasts need during 2024; therefore, DRAH's project timetable is most consistent with the SMFP planning horizon for the need determined acute care beds and the most effective alternative of all the applications in increasing access to the service area immediately.

UNC Rex's project will not operationalize the proposed beds until July 1, 2025, two years later compared to DRAH. As described later in this document, UNC Rex fails demonstrate conformity with all applicable review criteria. Therefore, UNC Rex cannot be an effective alternative.

Historical Utilization

Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor. Three applicants submitted four CON applications in this competitive review, DUHS, Rex Hospital, and WakeMed. All three applicants operate licensed acute care hospitals in the acute care service area, i.e., Wake County.

The need for additional acute care beds in the 2022 SMFP is triggered by the utilization of the total number of existing and approved acute care beds within a given service area. To project inpatient days of care in 2024, the total annual percentage of change over each of the last five fiscal years are divided by four to determine the historical percentage change for the county. For positive annual percentages of change, as is the case for Wake County, add one to determine the county growth rate multiplier. For counties with positive county growth rate multiplier, 2024 projected days of care are calculated by compounding the growth rate multiplier over the next four years. Wake County's growth rate multiplier is 1.0306, which is applied to project days of care during 2024. The projected average daily census (ADC) is then calculated by dividing the projected number of inpatient acute care days of care in 2024 by 365 days.

Facility Name	Licensed Acute Care Beds	Adjustments for CONs	FY2020 IP DOC	County Growth Rate Multiplier	Projected Days of Care	2024 Projected ADC
Duke Green Level Hospital	0	40				-40.0
Duke Raleigh Hospital	186	-40	50,222	1.0306	56,659	155
DUHS Total	186	-40	50,222	1.0306	56,659	155
Rex Hospital	439	50	121,590	1.0306	137,174	376
WakeMed	628	36	168,950	1.0306	190,605	522
WakeMed Cary Hospital	178	30	47,898	1.0306	54,037	148
WakeMed Total	806	66	216,848	1.0306	244,642	670

Source: 2022 SMFP, Table 5A: Acute Care Bed Need Projections

The ADC is then multiplied by the appropriate target occupancy factor, listed in the table below, to determine the number of beds needed to meet the projected demand.

ADC	Occupancy Factor
ADC <100	1.5
ADC 100-200	1.4
ADC >200 and ≤400	1.33
ADC >400	1.28

The following table summarizes the projected bed deficit/(surplus) for each applicant in Wake County based on the acute care bed methodology. **Facility Name**	**2022 Acute Care Beds (Existing & Approved)**	**2024 Projected ADC**	**2024 Beds Adjusted for Target Occupancy**	**Projected 2024 Deficit or (Surplus)**
Duke Green Level Hospital	40	0	0	-40.0
Duke Raleigh Hospital	146	155	217	71.2
DUHS Total	186	155	217	31.2
Rex Hospital*	489	376	499	10.5
WakeMed	664	522	668	4.0
WakeMed Cary Hospital	208	148	207	-0.9
WakeMed Total	872	670	875	**3.1**
Wake County Service Area Bed Deficit				**44.8**

Source: Table 5A, 2022 SMFP

Of the existing acute care hospitals in Wake County, DRAH has the smallest number of licensed beds and the largest projected acute care bed deficit during 2024 based on the 2022 SMFP methodology. Therefore, DRAH is the most effective alternative regarding historical utilization.

Competition (Patient Access to a New or Alternative Provider)

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer acute care beds than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.[3]

As of the beginning date for this review period, there are 1,547 existing and approved acute care beds, allocated between six existing and approved hospitals owned by three providers (DUHS, UNC, and WakeMed) in the Wake County Service Area, as illustrated in the following table.

Facility Name	2022 Acute Care Beds (Existing & Approved)
Duke Green Level Hospital	40
Duke Raleigh Hospital	186-40 = 146
DUHS Total	**186**
UNC Rex Hospital*	**468**
WakeMed	610
WakeMed Cary Hospital	200
WakeMed Total	**810**
Wake County Total	**1,464**

Source: Table 5A, Proposed 2023 SMFP

WakeMed currently controls 810 of the 1,464 acute care beds in Wake County, or 55.3 percent. UNC Rex currently controls 468 of the 1,464 acute care beds in Wake County, or 32 percent. DUHS controls only 186 of the acute care beds in Wake County, or 12.7%.

If either WakeMed Garner, UNC Rex, or UNC Holly Springs Hospital are approved to develop additional acute care beds in Wake County, the respective systems will continue to control a higher percentage of acute care beds in Wake County than DUHS.

Therefore, with regard to patient access to a new or alternate provider, the application submitted by DRAH is the most effective alternative, and the applications submitted by UNC Rex, UNC Rex Holly Springs Hospital, and WakeMed Garner are less effective alternatives.

[3] See also Agency analysis of Competition in 2021 Mecklenburg Acute Care Bed Review

Access By Service Area Residents

On page 32, the 2022 SMFP defines the service area for acute care beds as "the acute care bed service area in which the bed is located. The acute care bed service areas are the single and multicounty groupings shown in Figure 5.1." Figure 5.1, on page 36, shows Wake County as a multi-county acute care bed service area. Thus, the service area for this review is Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Projected Service to Wake County Residents, Project Year 3

	UNC Rex Hospital	UNC Rex Hospital Holly Springs	Duke Raleigh Hospital	WakeMed Garner Hospital
# of Wake County Patients	20,378	3,413	7,238	1,471
% of Wake County Patients	66.0%	79.8%	63.1%	51.1%

The number and percentage of Wake County patients projected to be served by each facility varies based on size and scope. Additionally, the acute care bed need determination methodology is based on utilization of all patients that utilize acute care beds in Wake County and is not only based on patients originating from Wake County. Wake County is an urban county and hosts the largest number of county residents in the state with three large health systems plus numerous smaller healthcare groups.

Considering these facts and the Agency's determination in the 2021 Mecklenburg County Acute Care Bed Review, DUHS believes that in this specific instance, attempting to compare the applicants based on the projected acute care bed access of Wake County residents has little value in reflecting comparative value to patients.

Access By Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid admissions as a percentage of total patients
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid cases per patient

The above metrics the Agency uses are determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for the applicants.

Projected Charity Care – 3rd Full FY

	Form F.2b	Form C.1b		Form F.2b	
Applicant	**Total Charity Care**	**Discharges**	**Avg Charity Care per Discharge**	**Gross Revenue**	**% of Gross Revenue**
UNC Rex Hospital	$5,928,785	30,876	$192	$258,600,396	2.3%
UNC Rex Hospital Holly Springs	$462,099	4,277	$108	$29,541,611	1.6%
Duke Raleigh Hospital	**$18,605,396**	**11,471**	**$1,622**	**$511,822,593**	**3.6%**
WakeMed Garner Hospital	$8,606,812	2,879	$2,990	$153,597,373	5.6%

Based on a comparison of average charity care per discharge and charity care percentage of gross revenues, the WakeMed Garner application is an effective alternative. However, WakeMed Garner proposes to develop only nine of the 45 need determined acute care beds. Even in a scenario where WakeMed Garner were approved, 36 acute care beds could be approved among the other applicants. As shown in the previous table, DRAH is also an effective alternative regarding access by charity care. UNC Rex Hospital and UNC Rex Holly Springs Hospital are the least effective alternatives regarding access by charity care.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicare Revenue – 3rd Full FY

Applicant	Form F.2b Total Medicare Revenue	Form C.1b Discharges	Avg Medicare Rev. per Discharge	Form F.2b Gross Revenue	% of Gross Revenue
UNC Rex Hospital	$145,278,830	30,876	$4,705	$258,600,396	56.2%
UNC Rex Hospital Holly Springs	$7,639,931	4,277	$1,786	$29,541,611	25.9%
Duke Raleigh Hospital	**$312,224,297**	**11,471**	**$27,219**	**$511,822,593**	**61.0%**
WakeMed Garner Hospital	$57,591,541	2,879	$20,004	$153,597,373	37.5%

As shown in the previous table, DUH is the most effective alternative with respect to average Medicare revenue per discharge and Medicare gross revenue as a percentage of total gross revenue.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicaid Revenue – 3rd Full FY

Applicant	Form F.2b Total Medicaid Revenue	Form C.1b Discharges	Avg Medicaid Rev. per Discharge	Form F.2b Gross Revenue	% of Gross Revenue
UNC Rex Hospital	$24,231,761	30,876	$785	$258,600,396	9.4%
UNC Rex Hospital Holly Springs	$2,819,175	4,277	$659	$29,541,611	9.5%
Duke Raleigh Hospital	$40,498,154	11,471	$3,530	$511,822,593	7.9%
WakeMed Garner Hospital	$22,586,506	2,879	$7,845	$153,597,373	14.7%

Based on a comparison of average Medicaid revenue per discharge and Medicaid percentage of gross revenues, the WakeMed Garner application is an effective alternative. However, WakeMed Garner proposes to develop only nine of the 45 need determined acute care beds. In a scenario where WakeMed

Garner were approved, 36 acute care beds could be approved among the other applicants. DUHS would note there are serious concerns regarding the reasonableness of WakeMed Garner's projected revenues. See DUHS's comments specific to the WakeMed Garner application later in this document.

The applications submitted by UNC Rex and UNC Rex Holly Springs Hospital do not conform to all statutory review criteria. Thus, UNC Rex and UNC Rex Holly Springs Hospital cannot be effective alternatives for this comparative.

DRAH is an effective alternative regarding access by Medicaid patients. In addition, DRAH's revenue projections are based on adult acute care beds only, therefore, its Medicaid revenues may be somewhat lower compared to other facilities whose pro formas reflect pediatric patients.

Projected Average Net Revenue per Patient

The following table shows the projected average net revenue per patient in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Patient – 3rd Full FY

Applicant	Form C.1b Discharge	Form F.2b Net Revenue	Average Net Revenue per Discharge
UNC Rex Hospital	30,876	$84,577,799	$2,739
UNC Rex Hospital Holly Springs	4,277	$9,630,154	$2,252
Duke Raleigh Hospital	11,471	$153,597,373	$13,390
WakeMed Garner Hospital	2,879	$38,508,532	$13,376

However, average net revenues for inpatient hospital stays based solely on total discharges do not provide a useful basis for direct comparison, due to differences in the acuity level of patients, length of stay, service required and the level of care at each facility. For example, DUHS included the entire inpatient stay in Form F.2 and F.3, which includes surgical as well as medical stays. Surgical stays, which make up a high percentage of DRAH's total, necessarily have higher costs and charges than a medical stay. DRAH has a high volume of total joint replacement cases, which have higher costs than other procedures.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per Patient – 3rd Full FY

Applicant	Form C.1b Discharge	Form F.2b Operating Expense	Average Operating Expense per Discharge
UNC Rex Hospital	30,876	$183,809,070	$5,953
UNC Rex Hospital Holly Springs	4,277	$13,965,702	$3,265
Duke Raleigh Hospital	11,471	$260,610,772	$22,719
WakeMed Garner Hospital	2,879	$25,847,201	$8,978

As with average net revenues, average operating costs for inpatient hospital stays based solely on total discharges do not provide a useful basis for direct comparison, due to differences in the acuity level of patients, length of stay, service required and the level of care at each facility. The costs for a stay that includes surgery are typically higher than those for medical patients. DRAH's operating costs also include an allocation of overhead expenses. Each applicant's costs will necessarily vary based on the assumptions and methodologies for allocating overhead expenses and other internal accounting. Therefore, a comparison of projected operating expense per patient is inconclusive.

Summary

The following table lists the comparative factors and states which application is the more effective alternative.

Comparative Factor	DRAH	UNC Rex	UNC Rex Holly Springs	WakeMed Garner
Conformity with Review Criteria	Yes	No	No	No
Scope of Services	**More Effective**	Not approvable	Less Effective	Less Effective
Geographic Accessibility	**More Effective**	Not approvable	Not approvable	Not approvable
Historical Utilization	**Most Effective**	Least Effective	Least Effective	Least Effective
Enhance Competition	**Most Effective**	Least Effective	Least Effective	Least Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups				
Projected Charity Care	**Most Effective**	Least Effective	Least Effective	Least Effective
Projected Medicare	**Most Effective**	Least Effective	Least Effective	Least Effective
Projected Medicaid	Less Effective	Less Effective	Less Effective	Nonconforming
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive

For each of the comparative factors previously discussed, DRAH's application is determined to be the most or more effective alternative for the following factors:

- Conformity with Review Criteria
- Scope of Services
- Geographic Accessibility
- Historical Utilization
- Enhance Competition
- Charity Care Access
- Medicaid Access

With regard to acute care beds, the application submitted by Duke Raleigh Hospital ("DRAH") is comparatively superior and should be approved as submitted.

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Case
- Projected Average Total Operating Cost per Case
- Patient Access to Lower Cost Surgical Services

The following additional factors are suggested for operating room proposals.

- Patient Access to Lower Cost Surgical Services
- Multispecialty versus Specialty

Other comparative factors may be utilized based on the facts of the competitive review. The following summarizes the competing applications relative to the potential comparative factors.

Conformity to CON Review Criteria

Six CON applications have been submitted seeking to develop ORs in Wake County. The applicants collectively propose to develop nine additional ORs in Wake County. Based on the 2022 SMFP's need determination, only two ORs can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the applications submitted by DUHS demonstrate conformity to all Criteria:

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
Duke Health Green Level ASC	**J-12261-22**	**Yes**
Oakview ASC	J-12252-22	No
Triangle Vascular Care	J-12253-22	No
Rex Hospital	J-12260-22	No
KM Surgery Center	J-12248-22	No
WakeMed Garner Hospital	J-12264-22	No

The Duke Health Green Level ASC application is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the Duke Health Green Level ASC application is the most effective alternative in this competitive review.

Scope of Services

The following table shows each applicant's projected scope of services (surgical specialties) to be provided at the proposed facilities. Generally, the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor.

Facility Type	ASC	ASC	Hospital	ASC	ASC	Hospital
Surgical Specialty	Oakview ASC	Triangle Vascular Care	Rex Hospital	Duke Health Green Level ASC	KM Surgery Center	WakeMed Garner Hospital[4]
Cardiothoracic			X			
Cardiovascular			X			
Gastroenterology			X			X
General Surgery			X	X	X	X
Gynecology			X	X		
Obstetrics			X			
Open Heart Surgery			X			
Ophthalmology	X		X	X	X	X
Oral Surgery			X			
Orthopedic			X	X		X
Otolaryngology			X	X	X	X
Neurology/Spine			X	X		
Pain Management			X		X	
Pediatrics			X			
Plastic Surgery			X	X	X	X
Podiatry			X	X		
Pulmonary			X			
Thoracic			X			
Urology			X	X	X	X
Vascular		X	X	X		

Regarding this factor, generally speaking the Agency has previously considered the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor. However, some surgical specialties cannot be performed in freestanding ASCs, for example, open heart surgery and obstetrics. Additionally, while many outpatient surgical services can be performed in an OR located at an ASF, not all of them are appropriate for an OR located at an ASF. Therefore, comparing hospital vs ASC proposals may be of little value for this comparative. Duke Health Green Level ASC's

[4] Application page 195 states WakeMed Garner Hospital excluded cardiothoracic surgery, cardiovascular surgery, donor services, neurosurgery, thoracic surgery, vascular surgery, pulmonary surgery, OB/GYN, dental/oral surgery, and pediatrics.

project has the broadest scope of services among the proposed ASCs and is the most effective among the ASC applications.

Patient Access to Lower Cost Surgical Services

ORs can be licensed as part of a hospital or an ASF. Many outpatient surgical services can be appropriately performed in either a hospital-based OR (either shared inpatient/outpatient ORs or dedicated ambulatory surgery ORs) or in an OR located at an ASF. However, the cost for that same service can be higher if performed in a hospital-based OR or, conversely, less expensive if performed in an OR located at an ASF. While many outpatient surgical services can be performed in an OR located at an ASF, not all of them are appropriate for an OR located at an ASF, and inpatient surgical services must be performed in a hospital-based OR.

The following table identifies the existing and approved inpatient, outpatient/dedicated ambulatory, and shared inpatient/outpatient ORs in Wake County.

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs	% OP of Total ORs	Shared ORs	% Shared of Total ORs
Wake County ORs	115	14	12.2%	41	36.6%	71	61.7%

Source: Proposed 2023 SMFP
*Includes existing and approved ORs and excludes dedicated C-Section and designated trauma ORs.

The table below shows the percentage of total Wake County surgical cases that were outpatient surgeries in FFY 2020, based on data reported in the 2022 SMFP.

Outpatient Surgical Cases as Percent of Total Wake County Surgical Cases					
Facility	Type of ORs	IP Cases	OP Cases	Total Cases	OP %
Duke Raleigh Hospital	Hospital/Shared	3,369	6,575	9,944	66%
Rex Surgery Center of Cary	ASF	0	3,810	3,810	100%
Raleigh Orthopaedic Surgery Center	ASF	0	4,126	4,126	100%
Rex Surgery Center of Wakefield	ASF	0	2,325	2,325	100%
Rex Hospital	Hospital/Shared	7,631	10,839	18,470	59%
Capital City Surgery Center	ASF	0	6,055	6,055	100%
WakeMed	Hospital/Shared	7,952	11,194	19,146	58%
WakeMed Cary Hospital	Hospital/Shared	2,867	3,681	6,548	56%
Blue Ridge Surgery Center	ASF	0	4,938	4,938	100%
Raleigh Plastic Surgery Center	ASF	0	303	303	100%
Triangle Orthopaedic Surgery Center	ASF	0	2,497	2,497	100%
Holly Springs Surgery Center	ASF	0	2,266	2,266	100%
Wake County Total		**21,819**	**58,609**	**80,428**	**73%**

As the table above shows, an average of 73% percent of the total Wake County surgical cases in FFY 2020 were outpatient surgical cases. Therefore, projects proposing the development of dedicated ambulatory surgery ORs would represent more effective alternatives.

Therefore, the applications submitted by Duke Health Green Level ASC, Oakview ASC, Triangle Vascular Care, and KM Surgery Center are the more effective proposals with respect to this comparative factor and the applications submitted by UNC Rex Hospital and WakeMed Garner are less effective with respect to this comparative factor.

Geographic Accessibility

The following table identifies the existing and approved Wake County operating rooms by location and facility name. As the table below shows, the existing and approved Wake County operating rooms are located in Raleigh, North Raleigh, Cary, Garner, and Holly Springs.

Wake County Existing and Approved Operating Rooms by Location

Location	Facility Name	Adjusted Operating Room Planning Inventory*
Holly Springs	Rex Hospital Holly Springs	3
North Raleigh	Rex Surgery Center of Wakefield	2
Cary	Rex Surgery Center of Cary	4
Raleigh	UNC REX Hospital	25
Raleigh	Raleigh Orthopedic Surgery Center	4
Cary	Raleigh Orthopedic Surgery-West Cary	1
Garner	Orthopaedic Surgery Center of Garner	1
Raleigh	Capital City Surgery Center	7
Raleigh	WakeMed	20
North Raleigh	WakeMed North Hospital	4
North Raleigh	WakeMed Surgery Center-North Raleigh	1
Cary	WakeMed Cary Hospital	10
Cary	WakeMed Surgery Center-Cary	1
Holly Springs	Holly Springs Surgery Center	3
Raleigh	Blue Ridge Surgery Center	6
Raleigh	Raleigh Plastic Surgery Center	1
Raleigh	Triangle Orthopedic Surgery Center	3
Raleigh	RAC Surgery Center	1
North Raleigh	OrthoNC Ambulatory Surgery Center	1
Raleigh	Wake Spine and Specialty Surgery Center	1
Raleigh	Duke Raleigh Hospital	15
Cary	Duke Health Green Level Ambulatory Surgery Center	1

Garner	Duke Health Garner Ambulatory Surgery Center	1
Raleigh	Duke Health Raleigh Ambulatory Surgery Center	
Raleigh	Surgical Center for Dental Professionals	2
Garner	Valleygate Surgery Center	1

*Adjusted operating room planning inventory from the Proposed 2023 State Medical Facilities Plan, Table 6B.

Wake County's existing operating rooms are widely disbursed. The applicants each propose to develop ORs in municipalities where there are existing ORs. Therefore, with regard to expanding geographic access to surgical services, all of the applications are equally effective alternatives because they all propose to develop the operating rooms in locations within the service area with existing surgical facilities. Duke's application is effective at increasing access in one of the fastest growing parts of the county.

Historical Utilization

Generally, the application submitted by the applicant with the highest utilization of its available surgical services is the more effective alternative with regard to this comparative factor.

UNC Rex Hospital is the only existing applicant with at least one complete fiscal year of historical utilization. The remaining applicants are not existing facilities and as such have no historical utilization. Therefore, this comparative is inconclusive.

Competition (Patient Access to a New or Alternative Provider)

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

DUHS acknowledges its status as an existing provider of surgical services in Wake County. WakeMed and UNC Rex are also existing providers of surgical services in Wake County. However, DRAH controls the smallest percentage of ORs among the health systems in the service area. Therefore, DUHS's proposal to develop two additional ORs at Duke Health Green Level ASC would more effectively enhance competition compared to the proposals by UNC Rex and WakeMed Garner.

Access by Service Area Residents

On page 50, the 2022 SMFP defines the service area for ORs as "…the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1." Figure 6.1, on page 55, shows Wake County as a single county OR service area. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area. Generally, the application projecting to serve the highest percentage of Wake County residents is the more effective alternative with regard to this comparative factor since the need determination is for two additional ORs to be located in Wake County.

However, the OR need determination methodology is based on utilization of all patients that inpatient and ambulatory surgical services in the Wake County service area and is not based on patients originating from Wake County. Further, Wake County is an urban county and the most populous county in the state. Wake County hosts three health care systems plus numerous smaller healthcare groups.

Considering these facts and the Agency's determination in the 2021 Durham County OR Review, DUHS believes that in this specific instance, attempting to compare the applicants based on the projected OR access of Wake County residents has little value.

Access By Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"*Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority*."

For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid admissions as a percentage of total patients
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid cases per OR

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for the applicants.

Projected Charity Care – 3rd Full FY

Applicant	Form F.2b Total Charity Care	Form C.1b Cases	Avg Charity Care per Case	Form F.2b Gross Revenue	% of Gross Revenue
Oakview ASC	$322,330	2,495	$129	$11,675,920	2.8%
Triangle Vascular Care	$79,670	841	$95	$13,278,366	0.6%
Rex Hospital	$24,051,877	22,776	$1,056	$772,325,837	3.1%
Duke Health Green Level ASC	$969,540	3,279	$296	$252,596,640	0.4%
KM Surgery Center	$1,186,252	1,164	$1,019	$24,503,292	4.8%
WakeMed Garner Hospital	$4,936,304	1,980	$2,493	$73,022,253	6.8%

Sources: Forms C and F.2 for each applicant

Differences in the acuity level of patients at each facility, the level of care (specialty ASF, multi-specialty ASC, and acute care hospital) at each facility, and the number and types of surgical services proposed by each of the facilities would make any comparison of little value.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicare Revenue – 3rd Full FY

Applicant	Form F.2b Total Medicare Revenue	Form C.1b Cases	Avg Medicare Rev. per Case	Form F.2b Gross Revenue	% of Gross Revenue
Oakview ASC	$7,463,187	2,495	$2,991	$11,675,920	63.9%
Triangle Vascular Care	$7,639,931	841	$9,084	$13,278,366	57.5%
Rex Hospital	$336,212,919	22,776	$14,762	$772,325,837	43.5%
Duke Health Green Level ASC	$17,131,645	3,279	$5,225	$252,596,640	6.8%
KM Surgery Center	$7,316,597	1,164	$6,286	$24,503,292	29.9%
WakeMed Garner Hospital	$29,938,614	1,980	$15,121	$73,022,253	41.0%

Sources: Forms C and F.2 for each applicant

Due to differences in the acuity level of patients at each facility, the level of care (specialty ASF, multi-specialty ASC, and acute care hospital) at each facility, and the number and types of surgical services proposed by each of the facilities would make any comparison of little value.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicaid Revenue – 3rd Full FY

Applicant	Form F.2b Total Medicaid Revenue	Form C.1b Cases	Avg Medicaid Rev. per Case	Form F.2b Gross Revenue	% of Gross Revenue
Oakview ASC	$49,589	2,495	$20	$11,675,920	0.4%
Triangle Vascular Care	$585,576	841	$696	$219,738,783	0.3%
Rex Hospital	$35,655,233	22,776	$1,565	$219,738,784	16.2%
Duke Health Green Level ASC	$1,419,298	3,279	$433	$219,738,785	0.6%
KM Surgery Center	$499,836	1,164	$429	$219,738,786	0.2%
WakeMed Garner Hospital	$10,240,535	1,980	$5,172	$219,738,787	4.7%

Sources: Forms C and F.2 for each applicant

Due to differences in the acuity level of patients at each facility, the level of care (specialty ASF, multi-specialty ASC, and acute care hospital) at each facility, and the number and types of surgical services proposed by each of the facilities would make any comparison of little value.

Projected Average Net Revenue per Surgical Case

The following table shows the projected average net surgical revenue per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Patient – 3rd Full FY

Applicant	Form C.1b Cases	Form F.2b Net Revenue	Average Net Revenue per Case
Oakview ASC	2,495	$6,797,443	$2,724
Triangle Vascular Care	841	$4,226,955	$5,026
Rex Hospital	22,776	$252,596,640	$11,090
Duke Health Green Level ASC	3,279	$15,663,253	$4,777
KM Surgery Center	1,164	$7,074,418	$6,078
WakeMed Garner Hospital	1,980	$16,377,138	$8,271

Sources: Forms C and F.2 for each applicant
*UNC does not provide separate financial projections for inpatient surgical services. Projected financial information is for all inpatients, including those who do not utilize surgical services.

Due to differences in the acuity level of patients at each facility, the level of care (specialty ASF, multi-specialty ASC, and acute care hospital) at each facility, and the number and types of surgical services proposed by each of the facilities would make any comparison of little value.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per Patient – 3rd Full FY

Applicant	Form C.1b Cases	Form F.2b Operating Expense	Average Operating Expense per Case
Oakview ASC	2,495	$5,374,757	$2,154
Triangle Vascular Care	841	$2,149,140	$2,555
Rex Hospital	22,776	$205,748,067	$9,034
Duke Health Green Level ASC	3,279	$11,289,982	$3,443
KM Surgery Center	1,164	$5,076,781	$4,361
WakeMed Garner Hospital	1,980	$16,923,587	$8,547

Sources: Forms C and F.2 for each applicant

Due to differences in the acuity level of patients at each facility, the level of care (specialty ASF, multi-specialty ASC, and acute care hospital) at each facility, and the number and types of surgical services proposed by each of the facilities would make any comparison of little value.

Summary

The following table lists the comparative factors and states which application is the more effective alternative.

Comparative Factor	Duke Health Green Level ASC	Oakview ASC	Triangle Vascular Care	Rex Hospital	KM Surgery Center	WakeMed Garner Hospital
Conformity with Review Criteria	**Yes**	No	No	No	No	No
Scope of Services	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Geographic Accessibility	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective
Access to Lower Cost Surgical Services	**More Effective**	Not approvable	Not approvable	Less Effective	Not approvable	Less Effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Enhance Competition	**More Effective**	Not approvable	Not approvable	Not approvable	Not approvable	Not approvable
Access by Service Area Residents	Not Evaluated	Not Evaluated	Not Evaluated	Not Evaluated	Not Evaluated	Not Evaluated
Access by Underserved Groups						
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

COMMENTS SPECIFIC TO OAKVIEW ASC
PROJECT ID No. J-12252-22

Oakview's proposal would create a new 1-OR, single-specialty ASC in the service area. Thus, the Oakview proposal will not provide meaningful access to an alternative provider in the service area. Additionally, with regard to providing Wake County patients with access to more multiple surgical specialties Oakview is the least effective alternative, as Oakview proposes to serve only ophthalmic surgical patients.

For these reasons and the reasons previously described in this document, the Oakview application is comparatively inferior to Duke Health Green Level ASC's CON application.

Criterion 3 "*The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed*."

Michael Kelly, MD has a minority ownership interest in Blue Ridge Surgery Center, an existing ASC in Wake County with available capacity. As demonstrated in Table 6B: Projected Operating Room Need for 2024 of the 2022 SMFP, Blue Ridge Surgery Center has a projected **surplus** of more than three OR (3.14). As described in Section Q of the Oakview application, Dr. Kelly performs two-thirds of his surgeries at Blue Ridge Surgery Center. Section C.4 describes the intentions of two other ophthalmologists who intend to perform cases at Oakview ASC, Preeya Gupta, MD and Vincent Dahringer, MD. Dr. Gupta is also on the Medical Staff at Blue Ridge Surgery Center. Dr. Kelly and Dr. Gupta essentially propose to shift their volume of ambulatory surgery cases from an existing, underutilized ASC to the proposed Oakview ASC. Therefore, the applicant failed to adequately demonstrate the need it has to develop a new OR in the service area.

Oakview will provide extremely limited access for medically underserved groups, specifically Medicaid patients. As illustrated in Section L.3, Oakview projects Medicaid patients will account for only 0.5% of projected patients. This equates to only **twelve Medicaid patient** during the third project year (.005 x 2,495 = 12). Oakview projects three physicians will utilize the proposed OR, with an average of 4 Medicaid patients per provider.

For these reasons, the application should be found non-conforming to Criterion 3.

Criterion 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*."

The Oakview application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

Michael Kelly, MD has a minority ownership interest in Blue Ridge Surgery Center, an existing ASC in Wake County with available capacity. As demonstrated in Table 6B: Projected Operating Room Need for 2024 of the 2022 SMFP, Blue Ridge Surgery Center has a projected **surplus** of more than three OR (3.14). As described in Section Q of the Oakview application, Dr. Kelly performs two-thirds of his surgeries at Blue Ridge Surgery Center. Section C.4 describes the intentions of two other ophthalmologists who intend to perform cases at Oakview ASC, Preeya Gupta, MD and Vincent Dahringer, MD. Dr. Gupta is also on the Medical Staff at Blue Ridge Surgery Center. Dr. Kelly and Dr. Gupta essentially propose to shift their volume of ambulatory surgery cases from an existing, underutilized ASC to the proposed Oakview ASC. Therefore, the applicant failed to adequately demonstrate that the proposed project will not result in unnecessary duplication of existing ASC.

Criterion 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."*

Based on the facts which result in Oakview being non-conforming with Criteria 1, 3, 4, and 6, it should also be found non-conforming with Criterion 18a.

COMMENTS SPECIFIC TO TRIANGLE VASCULAR CARE (TVC)
PROJECT ID No. J-12253-22

TVC's proposal would create a new 1-OR, single-specialty ASC and the second vascular access ASC in the service area. TVC and RAC are each affiliated with Azura Vascular Care, which is a subsidiary of Fresenius Medical Care.[5] Thus, the TVC proposal will not provide access to an alternative provider in the service area. Additionally, with regard to providing Wake County patients with access to more multiple surgical specialties TVC is the least effective alternative, as TVC proposes to serve only ESRD patients.

For these reasons and the reasons previously described in this document, the TVC application is comparatively inferior to Duke Health Green Level ASC's CON application.

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

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

TVC does not adequately demonstrate its proposal would maximize healthcare value. The vast majority of TVC's surgical cases during project year three are procedures that can be (and historically have been) performed in an office-based setting. To the extent that any of these reflect cases that would be more effectively performed in an ASC, there is already a dedicated vascular access ASC in Wake County that has capacity available. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Additionally, the applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 4, and 6. Therefore, the application is not conforming to this criterion and cannot be approved.

[5] Rhonda Palumbo, Director of Business Contracts, Azura Vascular Care is identified as the Contact Individual for TVC's CON application as well as RAC's CON applications J-11551-18 and J-11804-19.

Criterion 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*."

TVC failed to discuss the alternative of utilizing the existing vascular access ASC in Wake County, i.e., Raleigh Access Center (RAC). TVC and RAC are each affiliated with Azura Vascular Care, which is a subsidiary of Fresenius Medical Care. As reported in its 2022 License Renewal Application, RAC performed only 134 surgical cases in its licensed OR. Section D of RAC's 2022 License Renewal Application reports the average case time in minutes for ambulatory cases is only 30 minutes. Therefore, the RAC OR maintains an abundance of capacity for vascular access procedures. According to TVC's projected patient origin, the vast majority of patients that are expected to utilize the proposed OR will originate from outside Wake County (83%); therefore, the extent to which RAC's project will improve geographic access for service area residents for these procedures is negligible. TVC failed to provide any discussion of efforts to seek privileges at RAC or rationale describing why RAC is not an effective alternative for its patients.

Additionally, the TVC application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

TVC unnecessarily duplicates an existing vascular access ASC in Wake County, i.e., RAC. RAC operates an ASC with one OR focused on vascular access procedures for patients with end stage renal disease, Project IDs J-11551-18 and J-11804-19. TVC and RAC are each affiliated with Azura Vascular Care, which is a subsidiary of Fresenius Medical Care. As reported in its 2022 License Renewal Application, RAC performed only 134 surgical cases in its licensed OR. Section D of RAC's 2022 License Renewal Application reports the average case time in minutes for ambulatory cases is only 30 minutes. Based on the updated surgical case projections contained in J-11904-19, Therefore, the RAC OR maintains an abundance of capacity for vascular access procedures. TVC's response to Section G.2 fails to acknowledge the available capacity at RAC. Additionally, TVC failed to provide any discussion of efforts to seek privileges at RAC or rationale describing why RAC is not an effective alternative for its patients. Therefore, TVC failed to adequately demonstrate that its proposed vascular access OR will not result in unnecessary duplication of existing vascular access ORs in the service area.

Criterion 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."*

Based on the facts which result in TVC being non-conforming with Criteria 1, 4, and 6, it should also be found non-conforming with Criterion 18a.

TVC states the proposed OR is needed to reduce the cost of care to patients; however, the cost of care will actually be increasing for the majority of patients projected to be served by the proposed OR. Specifically, the cost of care for procedures performed in a licensed ASC (which charges a facility fee) are typically higher compared to the same procedures performed an office-based setting. Facility fees allow an ASC to bill patients a service charge for the patient's use of the ASC facility and equipment. In some cases, a patient may be responsible for the service bill if their insurance declines to pay or if the patient has a high deductible health plan. Patients receiving office-based services do not incur facility fees because the physician practice does have comparable overhead expense for performing the service. Approximately, the vast majority of TVC's cases during project year three are procedures that can be (and historically have been) performed in an office-based setting. Therefore, the cost of care will actually increase for these patients.

COMMENTS SPECIFIC TO UNC REX HOSPITAL
PROJECT ID No. J-12258-22 (ACUTE CARE BEDS)

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

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

UNC Rex fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 "*The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed*."

UNC Rex failed to provide any discussion regarding its assumptions for projecting average length of stay or the reasonableness of projected discharges. Form C.1 assumes the facility average length of stay will be 4.6 days through the third project year However, Form C Assumptions and Methodology contain no information describing why it is reasonable to assume the average length of stay will remain constant. Application page 52 states "UNC Rex has the highest Medicare CMI in Wake County, which is an indication that, on average, UNC REX Hospital is caring for more high acuity patients than any other hospital in the county." UNC Rex provides data from the American Hospital Directory reporting that during CY2020, its Medicare CMI was 2.10. DUHS obtained data from the American Hospital Director summarizing UNC Rex's Medicare CMI during recent years. See table below.

UNC Rex Medicare Case Mix Index

	FY 2018	FY 2019	FY 2020	FY 2021
Case Mix Index	1.9447	1.99	2.07	2.1039

Source: American Hospital Directory

UNC Rex's Medicare CMI has consistently increased since FY2018. Generally speaking, increased complexity is associated with comparatively longer lengths of stay. Therefore, it is reasonable to assume that UNC Rex's ALOS has increased in the recent past. In fact, upon review of licensure renewal data, UNC Rex's ALOS has increased significantly during recent years. See table below.

UNC Rex Historical Average Length of Stay

	FY2018	FY2019	FY2020	FY2021	CAGR
Acute Care Discharges	30,233	30,164	28,667	28,906	-1.5%
Days of Care	114,663	118,736	117,457	132,776	5.0%
ALOS	**3.8**	**3.9**	**4.1**	**4.6**	**6.6%**

Source: License Renewal Applications

It is unknown whether the increase in CMI and ALOS at UNC Rex is attributable to COVID patients.

UNC Rex projects that lower acuity days of care from the UNC Rex Holly Springs service area will shift to UNC Rex Holly Springs. Indeed, UNC Rex Holly Springs (J-12259-22) assumes an ALOS of 3.6 days. This assumption will necessarily result in a larger percentage of higher acuity discharges remaining at UNC Rex, which will also result in a comparatively higher ALOS than historically experienced at UNC Rex. Though no assumptions are provided for projecting acute care discharges at UNC Rex, DUHS assumes that discharges were calculated by dividing days of care by ALOS. By understating the projected ALOS, UNC Rex overstates its projected acute care discharges.

Therefore, absent any assumptions contained in the application as submitted regarding ALOS and methodology for projecting discharges at UNC Rex, the projected discharges are not supported.

On August 24, 2022, UNC Rex announced its intention to close its pediatric unit and its plans to convert its 10 pediatric beds to adult beds.[6] The conversion of beds was effective August 31, 2022. Therefore, UNC Rex was recently able to gain incremental adult acute care bed capacity – and eliminate any pediatric utilization; accordingly, its purported need for additional acute care beds is overstated.

For the foregoing reasons, the UNC Rex application does not conform to Criterion 3.

[6] https://abc11.com/unc-rex-hospital-pediatric-unit-closing-patients-raleigh/12170137/#:~:text=RALEIGH%2C%20N.C.%20(WTVD)%20%2D%2D,pediatric%20beds%20to%20adult%20beds.

Criterion 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*."

After filing its application, UNC Rex has already pursued an alternative not identified in its application to increase acute care bed capacity, by converting its 10 pediatric beds to adult beds, based on a low number of pediatric patients. This alternative to increase capacity by 10 beds for adults and eliminate services for pediatric patients – obviously considered effective enough to implement immediately – was not addressed in the application.

In addition, the UNC Rex application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 1, 3, 5, 6, and 18a.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the application being non-conforming to Criterion 5.

UNC Rex also failed to account for adequate costs to renovate the spaces where it proposes to develop incremental acute care bed capacity. See discussion regarding Criterion 12.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

UNC Rex did not adequately demonstrate that its proposal would not result in unnecessary duplication of acute care in Wake County. See discussion regarding projected utilization in Criterion 3. Therefore, the application is nonconforming to Review Criterion 6.

Criterion 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*."

UNC REX does not properly account for all necessary construction in its application. UNC REX proposes to renovate space to accommodate the incremental beds. It specifically identifies construction requirements and costs necessary to upgrade individual patient rooms to meet The Facilities Guidelines Institute requirements included in the 2022 edition, stating "renovation will also include all necessary electrical, HVAC, and plumbing work to meet current FGI Hospital Guidelines." The application identifies existing rooms on 4 West and 6 East to meet those requirements.

However, UNC REX does not identify any renovation to the units themselves. FGI characterizes projects modifying "an entire area," which would include a patient unit with multiple rooms, as "major renovation projects" that must meet the requirements for new construction to the extent possible. See FGI 2022 Section 1.1-3.1.12 (3). The proposed renovation of 6 East would appear to meet this definition, and therefore the entire space, not just the patient rooms, would be required to meet FGI 2022 2.1 (Common Elements for Hospitals) standards, including but not limited to:

2.1-2 Patient Care Units and other Patient Care Areas
Tables 2.1-1, 2.1-2, 2.1-3, Appendix Table A2.1-a
2.1-2.8.8.2
(1) Medication Preparation Room
(b) (ii) Handwashing station
2.1-2.8.9.2 Nourishment Area of Room Features
(1) Handwashing station
(2) Work Counter
(3) Refrigerator
(4) Microwave
(5) Storage Cabinets
(6) Space for temporary storage of food service implements
2.1-2.8.13.2 Equipment and supply storage room or alcove.
A room or alcove- sized to provide a minimum of 10 sf feet (0.93 square meter) per patient bed- shall be provided on the patient care unit floor for storage of equipment and supplies necessary for patient care.
2.1-2.10.1 Family and Visitor Lounge
Each patient care unit shall provide access to a lounge for family and visitor
2.1-2.10.1.1 Size
(2) In the absence of a functional program, the lounge shall be sized to accommodate at least 1.5 persons for every adult intensive care bed and one person for every four medical/surgical beds in the unit.
2.1-2.10.1.2 This lounge shall be immediately accessible to the patient care unit served.

The FGI guidelines are attached to these comments.

UNC REX did not include the costs of renovating all of these support spaces to meet these requirements. These renovations would also affect the construction timetable. These renovations also affect the feasibility of accommodating the same number of patient rooms on the unit.

Accordingly, the application is nonconforming with Criterion 12.

Criterion 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."*

Based on the facts which result in UNC Rex being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

10A NCAC 14C .3800

The UNC Rex application does not conform to 10A NCAC 14C .3803 because projected utilization is not based on reasonable and adequately supported assumptions. See discussion regarding projected utilization in Criterion 3.

COMMENTS SPECIFIC TO UNC REX HOLLY SPRINGS
PROJECT ID No. J-12259-22

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

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

The UNC Rex Holly Springs application fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 "*The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed*."

UNC Rex acute care days increased 6.8% from SFY19-SFY22.[7] However, UNC Rex failed to provide any discussion regarding discharges or average length of stay in relation to days of care during SFY19-SFY22.

UNC Rex assumes its acute care days from the UNC Rex Holly Springs service area will increase 7.0 percent annually, which is nearly three times higher than the projected growth rate UNC Rex utilized to project acute care days for its hospital (2.74%). The aggressive growth rate and assumption that 80 percent of UNC Rex Holly Springs service area patients will shift to the facility result in the following projections provided by the applicant.

[7] J-12259-22, Section Q, page 1

Projected UNC REX Holly Springs Hospital Days of Care

	SFY23	*SFY24*	*SFY25*	*SFY26**	*SFY27*	*SFY28*
UNC REX Holly Springs Hospital Acute Care Days	11,100	11,881	12,718	13,614	14,572	15,599
Licensed Acute Care Beds	50	50	50	59	59	59
Percent Occupancy	**60.8%**	**65.1%**	**69.7%**	**63.2%**	**67.7%**	**72.4%**

Source: J-12259-22, Section Q, page 7

UNC Rex Holly Springs Hospital has been operational less than one year.[8] In fact, as of August 15, 2022, UNC Rex Holly Springs Hospital has yet to open six of its approved acute care beds.[9] Based on annualized days of care during May 2022, acute care bed utilization at UNC Rex Holly Springs is only 38.6% of the operational 36 beds. See table below.

UNC REX Holly Springs Hospital Days of Care

	SFY22						
	Nov	*Dec*	*Jan*	*Feb*	*March*	*April*	*May*
Acute Care Days	185	352	444	366	374	321	431
Annualized Rate	**2,251**	**4,145**	**5,228**	**4,771**	**4,404**	**3,906**	**5,075**
Annualized ADC	6.2	11.4	14.3	13.1	12.1	10.7	13.9
Operational Beds	24	24	24	24	24	24	36
Occupancy	**25.7%**	**47.3%**	**59.7%**	**54.5%**	**50.3%**	**44.6%**	**38.6%**

Source: J-12259-22, Section Q, page 4

UNC Rex projects UNC Rex Holly Springs SFY22 annualized utilization will double from 5,075 days of care (based on May 2022) to 11,100 days of care during SFY23. The projected utilization assumes 60.8% occupancy of 50 beds during SFY23 despite a mere 38.6% occupancy of only 36 beds during SFY22 (based on May 2022 annualized).

UNC Rex Holly Springs SFY22 annualized utilization equates to only 38% of the appropriate days of care served by UNC Rex Hospital (5,075 ÷ 13,454) during SFY22.

	SFY19	*SFY20*	*SFY21*	*SFY22**
Acute Care Days	10,568	9,635	11,022	13,454

*Annualized based on 11 months of data.
Source: J-12259-22, Section Q, page 5

[8] UNC REX Hospital Holly Springs began serving patients on November 1, 2021. See page 33, J-12259-22.
[9] J-12259-22, Section Q, page 4

The expectation that 80% of appropriate days of care from the UNC Rex Holly Springs service area will immediately shift to the hospital during SFY23 and beyond is not supported.

UNC Rex failed to provide any discussion regarding average length of stay for UNC Rex Holly Springs. Form C.1 assumes an average length of stay increase from 2.9 during SFY22 to 3.6 during SFY23-SFY28 and a footnote to Form C.1 states, "ALOS is based on patients to be served from the UNC REX Holly Springs Hospital service area as detailed in Form C Assumptions and Methodology." However, Form C Assumptions and Methodology contain no information describing why the average length of stay increases or what assumptions were used to derive the ALOS projections. In fact, Form C Assumptions and Methodology contain no information describing how UNC Rex Holly Springs discharges were determined. Assumedly, UNC Rex Holly Springs projected discharges in Form C.1 were determined by dividing projected days of care by projected ALOS. However, such assumption is not contained in the application. Therefore, absent any assumptions contained in the application as submitted regarding ALOS and methodology for projecting discharges at UNC Rex Holly Springs, the projected discharges are not supported.

For the foregoing reasons, the UNC Rex Holly Springs application does not conform to Criterion 3.

Criterion 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*."

The UNC Rex Holly Springs application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 1, 3, 5, 6, and 18a.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the application being non-conforming to Criterion 5.

UNC Rex Holly Springs historical payor mix is not reliable because it is based on only seven months of data reflecting a staff up by unit, e.g. labor and delivery. Therefore, the limited available payor mix is not representative of ongoing and future operations.

A comparison of average operating expenses per discharges indicates UNC Rex Holly Springs projected operating expenses are abnormally low for such a small acute care hospital. See the following table.

Comparison of Average Operating Expenses per Discharge – 2022 Wake County Acute Care Bed Review

Applicant	Form C.1b Discharge	Form F.2b Operating Expense	Average Operating Expense per Discharge
UNC Rex Hospital	30,876	$183,809,070	$5,953
UNC Rex Hospital Holly Springs	**4,277**	**$13,965,702**	**$3,265**
Duke Raleigh Hospital	11,471	$260,610,772	$22,719
WakeMed Garner Hospital	2,879	$25,847,201	$8,978

To evaluate the reasonableness of UNC Rex Holly Springs average operating expenses, DUHS assessed average operating expenses per discharge for a similar project proposed by UNC in Durham County. UNC-RTP received CON approval to develop new 40-bed hospital in Research Triangle Park. The following table summarizes average operating expenses per discharge based on information provided in UNC-RTP, Project ID J-012065-21.

Average Operating Expenses per Discharge – UNC-RTP, Project ID J-012065-21

UNC-RTP Inpatient Services	SFY26	SFY27	SFY28
Discharges (Form C)	1,048	1,624	2,238
Operating Expenses (Form F.3)	$22,879,125	$31,940,416	$42,521,459
Avg. OpEx per Discharge	$21,831	$19,668	$19,000

Source: Project ID J-012065-21

The difference between average operating expenses per discharge for UNC Rex Holly Springs and UNC-RTP is astounding even when depreciation is excluded from UNC-RTP's expenses. See the following table.

Average Operating Expenses per Discharge – UNC-RTP, Project ID J-012065-21

UNC-RTP Inpatient Services	SFY26	SFY27	SFY28
Discharges (Form C)	1,048	1,624	2,238
Operating Expenses Excluding Depreciation (Form F.3)	$16,796,633	$25,857,924	$36,438,967
Avg. OpEx per Discharge	$16,027	$15,922	$16,282

Source: Project ID J-012065-21

The drastic difference between average operating expenses per discharge for UNC Rex Holly Springs and UNC-RTP undermines the reasonableness of UNC Rex Holly Springs operating expenses. At a minimum, the Agency should not consider UNC Rex Holly Springs average operating expense per discharge in its comparative analysis.

Based on the previous discussion regarding UNC Rex's failure to provide assumptions to project ALOS and discharges at UNC Rex Holly Springs, the projected expenses and revenues are not reliable. Therefore, the application should be found non-conforming with Criterion 5.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

UNC Rex did not adequately demonstrate that its proposal would not result in unnecessary duplication of acute care services in Wake County. See discussion regarding utilization in Criterion 3. Therefore, the UNC Rex Holly Springs application is nonconforming to Review Criterion 6.

Criterion 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."*

Based on the facts which result in UNC Rex Holly Springs being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

10A NCAC 14C .3800

The UNC Rex Holly Springs application does not conform to 10A NCAC 14C .3803 because projected utilization is not based on reasonable and adequately supported assumptions. See discussion regarding projected utilization in Criterion 3.

COMMENTS SPECIFIC TO UNC REX HOSPITAL
PROJECT ID No. J-12260-22 (ORs)

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

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

UNC Rex fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 "*The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed*."

UNC Rex assumes its outpatient surgical cases will increase by 5.1% annually through the third project year. The projection is based on the facility's SFY16-SFY 22 annualized CAGR for outpatient surgical cases. However, much of the historical growth was experienced in SFY22.

	SFY16	***SFY17***	***SFY18***	***SFY19***	***SFY20***	***SFY21***	***SFY22****	***CAGR***
Outpatient Cases	11,259	10,720	10,898	11,705	10,901	12,892	15,166	5.1%
Annual Growth	NA	-4.8%	1.7%	7.4%	-6.9%	18.3%	17.6%	

Source: J-12260-22, Section Q, page 4
*Annualized based on 11 months of data

Pre-COVID, UNC Rex's outpatient surgical cases increased by a CAGR of only 1.4%. UNC Rex experienced a rebound in outpatient volume in SFY 21 and SFY 22 during which time inpatient surgical cases decreased. Therefore, a large portion of the SFY 21 and SFY 22 growth is likely attributable to the migration of inpatient surgical cases to the outpatient platform. Such migration typically results in a one-time adjustment to annual volume. In other words, the annual growth attributed to the migration of surgical cases from inpatient to outpatient is not expected to be replicated year after year. Therefore, UNC Rex's projected outpatient surgical case growth rate of 5.1% is overstated and unreliable.

UNC Rex projects outpatient surgical cases at Rex Surgery Center of Cary will decrease by 4.4% annually through the third project year, resulting in a surplus of 1.5 ORs at Rex Surgery Center of Cary. Therefore, UNC Rex could relocate one OR from Rex Surgery Center of Cary to UNC Rex Hospital instead of proposing to develop incremental OR capacity. Moreover, UNC Rex's presumed decrease in outpatient surgical utilization at Rex Surgery Center of Cary is inconsistent with its stated need for incremental surgical capacity.

For these reasons, the UNC Rex OR application does not conform to Criterion 3.

Criterion 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*."

The UNC Rex application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

UNC Rex projects outpatient surgical cases at Rex Surgery Center of Cary will decrease by 4.4% annually through the third project year, resulting in a surplus of 1.5 ORs at Rex Surgery Center of Cary. Therefore, a least costly and more effective alternative would be for UNC Rex to relocate one OR from Rex Surgery Center of Cary to UNC Rex Hospital instead of proposing to develop incremental OR capacity. Alternatively, UNC Rex could shift outpatient procedures from the hospital to the ASC, which is typically a more cost-effective alternative for ASC appropriate procedures.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding criteria 1, 3, 5, 6, and 18a.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

Based on the facts described in these written comments specific to Criterion 3 (incorporated herein by reference), these same facts result in the UNC Rex application being non-conforming to Criterion 5.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

UNC Rex did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Wake County. See discussion regarding projected utilization in Criterion 3. Therefore, the application is nonconforming to Review Criterion 6.

Criterion 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."*

Based on the facts which result in UNC Rex being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

10A NCAC 14C .2103

The UNC Rex application does not conform to 10A NCAC 14C .2103 because projected surgical utilization is not based on reasonable and adequately supported assumptions. See discussion regarding projected utilization in Criterion 3.

COMMENTS SPECIFIC TO WAKEMED GARNER
PROJECT ID No. J-12264-22

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

POLICY GEN-3: BASIC PRINCIPLES states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

WakeMed fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding criteria 3, 4, 5, 6, and 18a. Therefore, the application is not conforming to this criterion and cannot be approved.

Criterion 3 "*The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed*."

The 2022 SMFP projects the WakeMed system to have the greatest surplus of ORs (-2.64) of the existing health systems in the service area during FY2024. According to the 2022 SMFP OR methodology, WakeMed is projected to have a surplus of over three ORs at WakeMed Cary Hospital. Therefore, it would appear that the "most efficient and effective way to enhance access to care" would be to instead relocate existing hospital-based OR capacity from WakeMed Cary Hospital to the proposed WakeMed Garner Hospital.

WakeMed projects outpatient surgery cases from the WakeMed Garner service area by applying a "weighted population calculation" (2.33%) to FY2022 annualized non-tertiary outpatient surgical cases at each existing WakeMed acute care facility from the proposed service area. However, WakeMed failed to provide any historical data for outpatient surgery cases at each WakeMed acute care facility prior to FY2022 annualized to demonstrate whether a growth rate of 2.33% is reasonable and supported.

Additionally, WakeMed's "weighted population calculation" is based on the percentage of non-tertiary admissions by age group from the proposed service area. As shown on application page 185, approximately 43.2% of WakeMed's admissions from the proposed service area are age 65 and older. WakeMed did not provide historical outpatient surgery cases by age cohort to demonstrate whether a growth rate of 2.33% determined by a "weighted population calculation" is reasonable and supported. Absent this information, WakeMed Garner's outpatient surgery cases may be overstated for the proposed project.

Criterion 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*."

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. As previously described, the 2022 SMFP projects the WakeMed system to have the greatest surplus of ORs (-2.64) of the existing health systems in the service area during FY2024. According to the 2022 SMFP OR methodology, WakeMed is projected to have a surplus of over three ORs at WakeMed Cary Hospital. Therefore, it would appear that the "most efficient and effective way to enhance access to care" would be to instead relocate existing hospital-based OR capacity from WakeMed Cary Hospital to the proposed WakeMed Garner Hospital.

Criterion 5 *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."*

WakeMed Garner projects a positive net income during the first full year of the proposed project. Form F.2b projects the facility will have a positive net income of $11M during the first project year and that it will increase to $18M during the third project year. Such expectations are highly specious compared to other recent CON hospital projects and WakeMed's own experience.

In CON Project ID #J-12029-21, DUHS proposed to relocate 40 acute care beds from Duke Raleigh Hospital and develop a new 40-bed community hospital in southwest Wake County, Duke Green Level Hospital. Form F.2b projected a negative net income during each of the first three project years.

Form F.2b Projected Revenues and Net Income upon Project Completion DGLH – Entire Facility	1st Full FY F: 07/01/2026 T: 06/30/2027	2nd Full FY F: 07/01/2027 T: 06/30/2028	3rd Full FY F: 07/01/2028 T: 06/30/2029
Patient Services Gross Revenue			
Self Pay	12,735,844	18,033,455	26,509,534
Insurance *	52,189,895	76,039,857	110,456,604
Medicare *	72,594,331	104,292,955	151,537,323
Medicaid *	20,871,378	29,914,037	44,120,771
Other (Specify)	1,860,944	2,769,368	4,133,594
Total Patient Services Gross Revenue	160,252,392	231,049,672	336,757,827
Other Revenue (1)	5,370,687	7,496,570	10,943,972
Total Gross Revenue (2)	$165,623,079	$238,546,242	$347,701,798
Adjustments to Revenue			
Charity Care	6,402,034	9,219,357	13,449,850
Bad Debt	967,497	1,396,919	2,039,569
Contractual Adjustments	113,361,290	163,046,418	237,773,104
Total Adjustments to Revenue	120,730,821	173,662,694	253,262,523
Total Net Revenue (3)	44,892,258	64,883,549	94,439,275
Total Operating Costs (from Form F.3)	57,766,356	71,504,396	94,557,470
Net Income (4)	(12,874,099)	(6,620,848)	(118,195)

*** Including any managed care plans**

Source: J-12029-21

In CON Project ID # J-12065-21, UNC proposed to construct a new 40-bed hospital in Durham County, UNC-RTP. In that application, Form F.2b projected a negative net income during each of the first two project years.

Form F.2b Projected Revenues and Net Income upon Project Completion	1st Full FY	2nd Full FY	3rd Full FY
	F: 07/01/2026	F: 07/01/2027	F: 07/01/2028
UNC Hospitals-RTP Total Facility	T: 06/30/2027	T: 06/30/2028	T: 06/30/2029
Patient Services Gross Revenue[a]			
Self Pay	$12,043,895	$19,368,255	$27,708,908
Insurance *	$28,066,483	$45,469,162	$65,532,962
Medicare *	$36,676,352	$59,634,201	$86,230,255
Medicaid *	$13,613,337	$21,868,787	$31,256,132
Other (Other Govt.)	$3,869,423	$6,260,359	$9,010,527
Total Patient Services Gross Revenue	$94,269,490	$152,600,765	$219,738,783
Other Revenue (1)[b]			
Total Gross Revenue (2)	$94,269,490	$152,600,765	$219,738,783
Adjustments to Revenue			
Charity Care[c]	$11,527,232	$18,536,369	$26,517,350
Bad Debt[d]	$1,337,455	$2,165,034	$3,117,559
Contractual Adjustments[c]	$48,200,830	$78,096,125	$112,552,468
Total Adjustments to Revenue	$61,065,516	$98,797,529	$142,187,377
Total Net Revenue (3)	$33,203,974	$53,803,236	$77,551,406
Total Operating Costs (from Form F.3)	$40,622,703	$56,495,351	$75,137,868
Net Income (4)	($7,418,730)	($2,692,115)	$2,413,538

DUHS obtained inpatient charge, revenue, and cost data from the American Hospital Directory[10] to compare WakeMed's actual experience to the projected revenues and costs contained in the WakeMed Garner application. The following table summarizes 2021 charge and cost data for WakeMed Cary Hospital.

[10] The American Hospital Directory® provides data, statistics, and analytics about more than 7,000 hospitals nationwide. Hospital revenue and costs information is based on Medicare IPPS claims data.

Costs calculated per WakeMed Cary's cost report for the period ending 12/31/2021
Top 20 Base MS-DRGs

Base MS-DRG	Base MS-DRG Description	IPPS Cases	ALOS	Average Charges	Average Payment	Average Cost	Case Mix Index
872-871	Septicemia or severe sepsis w/o MV 96+ hours	251	5.9	$44,429	$10,254	$11,378	1.6119
179-178-177	Respiratory infections & inflammations	210	6.3	$44,560	$12,703	$12,642	1.7061
293-292-291	Heart failure & shock	182	4.4	$30,430	$7,438	$7,768	1.2038
379-378-377	G.I. hemorrhage	138	3.8	$40,817	$7,353	$8,773	1.1893
310-309-308	Cardiac arrhythmia & conduction disorders	137	3.3	$24,753	$4,748	$5,703	.7601
690-689	Kidney & urinary tract infections	124	4.3	$27,466	$5,481	$7,048	.8951
066-065-064	Intracranial hemorrhage or cerebral infarction	98	3.4	$38,175	$6,578	$7,336	1.0948
641-640	Misc disorders of nutrition,metabolism,fluids/electrolytes	96	4.0	$31,183	$5,816	$7,238	.9459
195-194-193	Simple pneumonia & pleurisy	88	4.8	$34,283	$6,293	$8,292	1.0231
392-391	Esophagitis, gastroent & misc digest disorders	84	4.0	$31,522	$5,134	$7,357	.8273
684-683-682	Renal failure	82	4.3	$31,056	$6,660	$7,680	1.0427
331-330-329	Major small & large bowel procedures	80	7.3	$98,382	$18,731	$20,992	2.9756
482-481-480	Hip & femur procedures except major joint	78	5.2	$79,865	$13,851	$17,821	2.1871
192-191-190	Chronic obstructive pulmonary disease	76	4.1	$30,414	$5,807	$7,887	.9854
189	Pulmonary edema & respiratory failure	66	4.8	$41,257	$7,693	$11,375	1.2248
603-602	Cellulitis	63	3.7	$23,051	$5,888	$6,637	.9387
390-389-388	G.I. obstruction	57	5.2	$33,372	$5,808	$8,125	.8337
855-854-853	Infectious & parasitic diseases w O.R. procedure	55	10.0	$108,840	$28,349	$26,141	4.2709
282-281-280	Acute myocardial infarction, discharged alive	53	4.6	$34,112	$6,958	$8,412	1.2297
812-811	Red blood cell disorders	49	4.2	$33,655	$5,062	$8,777	1.0321
	All Other Base MS-DRGs	1,468	5.0	$63,578	$12,298	$14,711	1.8357
	T O T A L S	**3,535**	**4.9**	**$50,548**	**$10,222**	**$11,992**	**1.5618**

Source: American Hospital Directory; Medicare IPPS claims data

Form F.2: Projected Revenues and Costs - WakeMed Garner

	PY1 FY27	PY2 FY28	PY3 FY29
Discharges	2,092	2,483	2,879
Gross Patient Service Revenue	$91,279,991	$109,065,571	$127,319,698
Net Revenue	$26,938,722	$32,586,927	$38,508,532
Operating costs	$18,862,878	$22,610,098	$25,847,201
Net Income	$8,075,844	$9,976,830	$12,661,332
Average Charge	**$43,633**	**$43,925**	**$44,224**
Average Payment	**$12,877**	**$13,124**	**$13,376**
Average Cost	**$9,017**	**$9,106**	**$8,978**

Source: J-12264-22, Form F.2 Inpatient Services

WakeMed Garner's projected annual average cost per discharge is drastically lower compared to WakeMed Cary's 2021 average cost per discharge which undermines the reasonableness of WakeMed Garner's projected expenses in Form F.3. WakeMed Cary's average cost per patient in 2021 ($11,992) is more than $3,000 higher compared to WakeMed Garner's projected average cost per patient in project year three ($8,978). This comparison of historical and proposed data would reveal that WakeMed Garner's projected expenses are significantly underestimated. Additionally, WakeMed Garner's average payment per discharge in year three ($13,376) is ~$3,000 higher compared to WakeMed Cary's 2021 average payment per discharge ($10,222).

WakeMed's strategy to inflate WakeMed Garner's average net revenue per discharge and diminish average cost per discharge results in generous projections of annual net income. In other words, if WakeMed instead utilized realistic projections of revenues and expenses based on historical experience, WakeMed Garner would not have a profitable net income during the project years. Consequently, the application does not conform to Criterion 5.

Criterion 6 "*The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities***."**

WakeMed did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Wake County. See discussion regarding projected utilization in Criterion 3. Therefore, the application is nonconforming to Review Criterion 6.

Criterion 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."

Based on the facts which result in the application being non-conforming with Criteria 1, 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a.

10A NCAC 14C .2103

The WakeMed application does not conform to 10A NCAC 14C .2103 because projected surgical utilization is not based on reasonable and adequately supported assumptions. See discussion regarding projected utilization in Criterion 3.

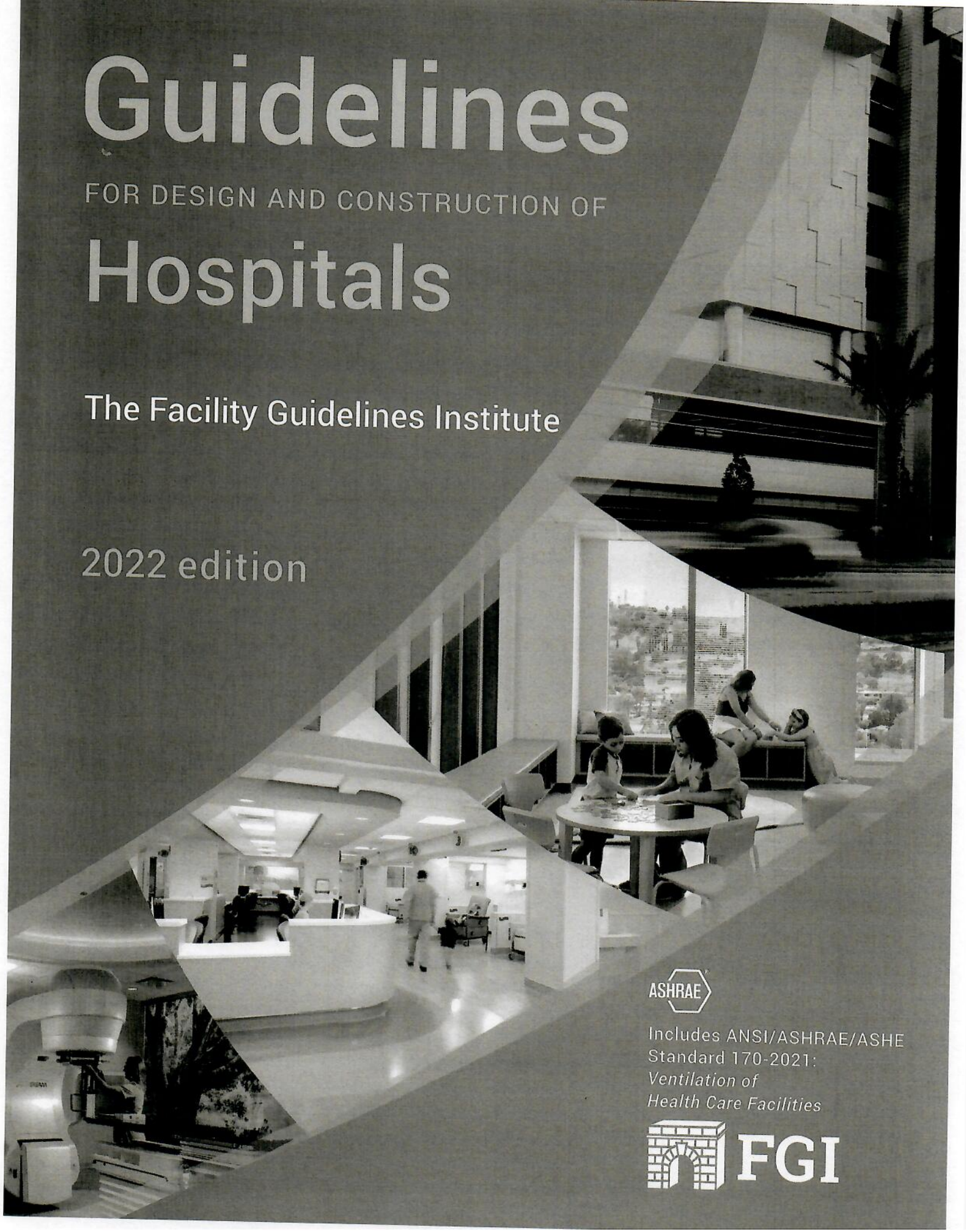
Guidelines

FOR DESIGN AND CONSTRUCTION OF

Hospitals

The Facility Guidelines Institute

2022 edition



ASHRAE

Includes ANSI/ASHRAE/ASHE Standard 170-2021: *Ventilation of Health Care Facilities*

FGI

1.1-3 Renovation

1.1-3.1 General

1.1-3.1.1 Compliance Requirements

1.1-3.1.1.1 Where renovation or replacement work is done in an existing facility, all new work or additions or both shall comply with applicable sections of the *Guidelines* and local, state, and federal codes.

1.1-3.1.1.2 Major renovation projects. Projects with any of the following scopes of work shall be considered a major renovation and shall comply with the requirements for new construction in the *Guidelines for Design and Construction of Hospitals* to the extent possible as determined by the authority having jurisdiction:

(1) A series of planned changes and updates to the physical plant of an existing facility
(2) A renovation project that includes modification of an entire building or an entire area in a building to accommodate a new use or occupancy
(3) Change in function in an area of an existing building for which the *Guidelines* for clinical spaces, clinical support areas, or infrastructure are different from those for the originally approved function.

1.1-3.1.1.3 Occupancy conversion [illegible] a building is converted from one occupan[illegible] another, it shall comply with the new consti[illegible] requirements.

1.1-3.1.1.4 Building system projects

(1) Only the altered, renovated, or modernized portion of an existing building system or individual component shall be required to meet the installation and equipment requirements in the *Guidelines*.
(2) When such construction impairs the performance of the balance of an affected building system, upgrades to that system shall be required beyond the limits of the project to the extent required to maintain existing operational performance.

*1.1-3.1.2 Exceptions

1.1-3.1.2.1 Where major structural elements make total compliance impractical or impossible, exceptions shall be considered.

***1.1-3.1.2.2** Minor renovation or replacement

APPENDIX

A1.1-3.1.2 Nonconforming conditions. When renovating or expanding existing facilities, it is not always practical or financially feasible to renovate or upgrade an entire existing facility to totally conform with requirements in the *Guidelines*. Therefore, authorities having jurisdiction are permitted to grant approval to renovate portions of a structure, space, or system if facility operations and patient safety in renovated and existing areas are not jeopardized by existing features of areas retained without complete corrective measures.

This recommendation does not guarantee an AHJ will grant an exception; it attempts to minimize restrictions on those improvements where total compliance would create an unreasonable hardship and would not substantially improve safety.

A1.1-3.1.2.2 Exceptions for minor renovation or replacement work. The project types described below are examples of minor renovation or replacement work that are not likely to reduce the level of health and safety in an existing building.

a. Routine repairs and maintenance to buildings, systems, or equipment. This project type does not require improvements to building features or systems.
b. Replacement of building furnishings and movable or fixed equipment. This project type only requires improvements to building systems that serve the equipment being replaced and only to the extent necessary to provide sufficient capacity for the replacement.
c. Minor changes to the configuration of an existing space do not require upgrade of the entire space.
d. Cosmetic changes or upgrades to an existing space do not require upgrade of the entire space.
e. Improvements to a building system or a space that cannot reasonably meet the requirements of this document should be permitted, provided the improvement does not impair other systems or functions of the building.
f. Existing systems that are not in strict compliance with the provisions of this document should be permitted to continue in use, unless the AHJ has determined that such use constitutes a distinct hazard to life.
g. Replacement of mechanical, electrical, plumbing, and fire protection equipment and infrastructure for maintenance purposes due to the failure or degraded performance of the components being replaced should be permitted, provided the health and safety in the facility is maintained at existing levels.

2.1-1.3.2 Parking

Parking provided shall comply with the general requirements in Section 1.3-3.4 (Site Features—Parking) and the specific requirements in each chapter.

■ 2.1-2 Patient Care Units and Other Patient Care Areas

2.1-2.1 General

*2.1-2.1.1 Application

The patient care unit and other patient care area requirements included in this section are common to most hospitals. For requirements specific to a hospital type, see the applicable hospital facility chapter.

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A2.1-2.1.1 Accommodations to encourage patient mobility. Patient care units should be designed to enhance opportunities for patient ambulation, including provision of ceiling track systems that support a harnessed patient walking with assistance (e.g., in patient unit corridors, a physical therapy clinic, and other patient rehabilitation service locations). See Section 1.2-4.7 (Patient Immobility Assessment) for more information about patient immobility prevention as a component of the safety risk assessment.

A2.1-2.1.2 Patient privacy

a. *Visual privacy.* Visual privacy can be achieved using various means, including cubicle curtains, blinds, and electronically controlled vision panels. In single-patient rooms, the entry room door can be used to achieve visual privacy provided the door is solid or has non-transparent glass. Where doors with vision panels or transparent glass are used, provisions for visual privacy should be made.
b. *Speech privacy.* Speech privacy should be addressed. Use of full-height partitions and/or sound-masking can enhance speech privacy.

A2.1-2.2 Equipment and architectural details for the patient room

a. *Standing assists.* Aids to help patients stand from seated positions (e.g., bedrails, grab bars, and extended chair armrests) should be available.
b. *Orientation of TV.* Space should allow for at least one television screen to be viewed from the patient chair, recliner, wheelchair, or other such device.
c. *Access to controls and communications.* Patient control of the environment should be accessible to the patient in a bed, patient chair, recliner, wheelchair, or other such device.

*2.1-2.1.2 Patient Privacy

Provisions shall be made to address patient visual and speech privacy.

*2.1-2.2 Patient Room

2.1-2.2.1 General

2.1-2.2.1.1 Capacity. See facility chapters for specific requirements.

2.1-2.2.1.2 Fall-safe provisions. Where indicated by the safety risk assessment (SRA), fall-safe provisions such as handrails and grab bars shall be included in the patient room, patient toilet room, and patient care unit corridors. See sections 2.1-7.2.2.9 (Grab bars) and 2.1-7.2.2.10 (Handrails) for information.

*2.1-2.2.2 Space Requirements

d. *Trip hazards.* Chair legs should not extend laterally or forward beyond the chair seat.

A2.1-2.2.2 Space considerations for patient mobility. Patient rooms should be sized, arranged, and furnished to maximize safe patient mobility, mobilization, weight-bearing exercise, and ambulation potential while minimizing risk to caregivers. This should apply for patients of all sizes and conditions described in the functional program.

Clearances should be provided and maintained to accommodate safe patient mobility and mobilization of patients. Designated clearances should not be obstructed by any object that does not qualify as movable according to appendix section A1.4-2 (Equipment types). Particular attention should be given to the following:

a. *Furniture and equipment size.* Furnishings and equipment (e.g., beds, exam tables, exam chairs, gurneys) affect clearance requirements. As furnishings and equipment vary based on clinical needs, patient size, manufacturer, and model, it is important that furnishings and equipment be selected for planning purposes by the operator of the facility.
b. *Sizing of patient rooms to accommodate clearances for patient chairs, etc.* The size of patient rooms should allow unimpeded clearance on at least one side and at the front of any patient chair, recliner, wheelchair, or other such device. The clearances may share bed clearance space.

For additional information on sizing patient rooms and selecting equipment for individuals of size, refer to the second edition of the "Patient Handling and Mobility Assessments" white paper posted on the Facility Guidelines Institute website.

2.1-2.2.2.1 Area. Minor encroachments (including columns and corridor door swing) that do not interfere with functions as determined by the AHJ shall be permitted to be included when determining minimum clear floor area requirements for a patient room.

2.1-2.2.2.2 For other space requirements, see facility chapters.

2.1-2.2.3 Windows

See Section 2.1-7.2.2.5 (Windows in patient rooms) for requirements. For behavioral and mental health hospital and patient care unit requirements, see Section 2.5-7.2.2.5 (Windows) in Chapter 2.5, Specific Requirements for Behavioral and Mental Health Hospitals.

2.1-2.2.4 Patient Privacy

For requirements, see Section 2.1-2.1.2 (Patient Privacy).

2.1-2.2.5 Handwashing Station in the Patient Room

2.1-2.2.5.1 Location. A handwashing station shall be provided in the patient room in addition to that in the toilet room.

(1) This handwashing station shall be located at or adjacent to the entrance to the patient room with unobstructed access for use by health care personnel and others entering and leaving the room.
(2) When multiple-patient rooms are permitted, this station shall be located outside the patients' cubicle curtains.

2.1-2.2.5.2 Design requirements. See Section 2.1-2.8.7.2 (Handwashing Station—Design requirements).

2.1-2.2.5.3 Renovation. In renovations of existing facilities, a handwashing station shall be provided in the patient room unless it is technically infeasible, or space does not permit the installation. In this situation, a handwashing station shall be provided in the toilet room and a hand sanitation dispenser shall be provided in the patient room.

2.1-2.2.6 Patient Toilet Room

*__2.1-2.2.6.1 General.__ Where required by other sections of the *Guidelines*, each patient shall have access to a toilet room without having to enter a corridor.

2.1-2.2.6.2 In patient care units, the patient toilet room shall serve no more than one patient room.

2.1-2.2.6.3 Room features. The patient toilet room shall be equipped with the following:

(1) A toilet
(2) A handwashing station. See Section 2.1-2.8.7 (Support Areas for Patient Care Units and Other Patient Care Areas—Handwashing Station) for requirements.
(3) A human-waste disposal system. See Section 2.1-8.4.3.7 (Plumbing Systems—Human waste disposal systems) for requirements.

2.1-2.2.7 Patient Bathing Facilities

2.1-2.2.7.1 Bathing facilities shall be provided in the following locations:

(1) The toilet room directly accessible from each patient room or
(2) A central bathing facility

2.1-2.2.7.2 Where a central bathing facility is provided, it shall meet the following requirements:

(1) General. Each bathtub or shower shall be in an individual room or enclosure that provides privacy for bathing, drying, and dressing.
(2) Number. Where individual bathing facilities are not provided in toilet rooms that are directly accessible from patient rooms, at least one shower or bathtub shall be provided for each patient care unit.
(3) The following shall be provided in or directly accessible to each central bathing facility.
    (a) Toilet. The toilet shall be enclosed if the room is designed for more than one patient at a time.
    (b) Handwashing sink
    (c) Storage for soap and towels

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A2.1-2.2.6.1 Visual cueing should be provided for toilet/bathing facilities in patient rooms. Cueing tools such as lighting and line of sight may aid orientation for those with cognitive impairment.

2.1-2.2.7.3 Where mobile lifts, shower gurney devices, wheelchairs, and other portable wheeled equipment will be used, the following requirements shall be met:

(1) Doorways shall be designed to allow entry of portable/mobile mechanical lifts and shower gurney devices.
(2) Thresholds shall be designed to facilitate use and prevent tipping of wheelchairs and other portable wheeled equipment.
(3) Patient shower rooms shall be designed to allow entry of portable/mobile mechanical lifts and shower gurney devices.
(4) Floor drain grates shall be designed to facilitate use and prevent tipping of wheelchairs and other portable wheeled equipment.

2.1-2.2.8 Patient Storage

Each patient room shall have a separate wardrobe, locker, or closet suitable for garments and for storing personal effects.

2.1-2.2.9 Building System Components

2.1-2.2.9.1 Electrical receptacles. See Table 2.1-1 (Electrical Receptacles for Patient Care Areas in Hospitals) for requirements.

2.1-2.2.9.2 Call systems. See Table 2.1-2 (Locations for Nurse Call Devices in Hospitals) for requirements.

2.1-2.2.9.3 Medical gas and vacuum systems. See Table 2.1-3 (Oxygen, Vacuum, Medical Air, WAGD, and Instrument Air Systems) for requirements.

2.1-2.3 Accommodations for Care of Individuals of Size

2.1-2.3.1 General

During hospital project planning, health care organizations shall determine their need to provide spaces designed to enable safe care of individuals of size as required in Section 1.2-6.4.1 (Projected Need for Accommodations for Care of Individuals of Size).

2.1-2.3.1.1 Application

(1) All patient care areas designated for care of individuals of size shall meet the requirements in this section.
(2) A patient handling and mobility assessment (Section 1.2-4.3) shall determine the need for expanded-capacity lifts and architectural details that support mobility of individuals of size in spaces where these patients may receive care. See sections 1.2-6.4.1.3 (Projected number of expanded-capacity lifts required) and 1.2-6.4.2 (Design Response for Accommodations for Individuals of Size).

2.1-2.3.1.2 Location. Spaces designated for care of or use by individuals of size shall be provided where they are needed to accommodate the population expected to be served by the facility.

*2.1-2.3.1.3 Patient lift system

(1) Accommodations for patient handling and mobilization shall be provided by either an overhead lift system or a floor-based full-body sling lift and standing-assist lifts.
(2) Lifts chosen shall be capable of accommodating the threshold weight capacity of individuals of size identified in the planning phase. See sections 1.2-4.3 (Patient Handling and Mobility Assessment) and 1.2-6.4.1.1 (Projected weight capacities for individuals of size in the population to be served).

2.1-2.3.2 Patient Room for Individuals of Size

The following shall apply to patient rooms designated for individuals of size.

2.1-2.3.2.1 General

(1) Capacity. All rooms designated for individuals of size shall be single-patient rooms.

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A2.1-2.3.1.3 Patient lift system. Overhead lift systems have some advantages over floor-based lifts. In addition to needing smaller room dimensions than floor-based lifts, overhead systems biomechanically impact the musculoskeletal system of health care providers less than floor-based models. As well, staff prefer and are more compliant in using overhead lifts, reducing the risk of musculoskeletal injury to staff and improving the quality of patient care.

*(d) Lighting. Task-specific lighting levels for health care settings recommended in the *U.S. Pharmacopeia-National Formulary* shall be used to design lighting.

*(e) Sharps containers shall be placed at a height that allows users to see the top of the container.

(f) Noise and sound. Medication safety zones shall meet the acoustic design criteria found in Section 1.2-6.1 (Acoustic Design).

***2.1-2.8.8.2 Work areas for preparing, dispensing, and administering medications**

(1) Medication preparation room

(a) This room shall be under visual control of the nursing staff.

(b) This room shall contain the following:

(i) Work counter
(ii) Handwashing station
(iii) Lockable refrigerator
(iv) Lockable storage for controlled drugs
(v) Sharps containers, where sharps are used

(c) Where a medication preparation room is used to store one or more self-contained medication-dispensing units, the room shall be designed with space to prepare medication when the self-contained medication dispensing units are present.

(d) Where a medication preparation room is used to compound sterile preparations, it shall meet the requirements in USP-NF General Chapter <797> "Pharmaceutical Compounding—Sterile Preparations."

(2) Medication-dispensing units, stations, and carts

(a) Use of self-contained medication-dispensing units (e.g., robotic devices used in pharmacies), automated medication-dispensing stations, mobile medication-dispensing carts, or other systems approved by the AHJ shall be permitted at the following locations provided the unit, station, or cart can be locked to secure controlled drugs:

(i) At a nurse station
(ii) In a clean workroom
(iii) In an alcove
(iv) In a patient room

(b) Where mobile medication-dispensing carts are used, space shall be provided to accommodate the cart.

(c) A handwashing station or hand sanitation dispenser shall be located next to stationary medication-dispensing units or stations.

2.1-2.8.9 Nourishment Area or Room

Each patient care unit shall have facilities for patient nourishment. Other patient care areas shall have facilities for patient nourishment as required in the facility chapters.

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A2.1-2.8.8.1 (2)(d) Detailed lighting recommendations for medication safety zone work areas can be found in USP-NF General Chapter <1066> "Physical Environments that Promote Safe Medication Use." Areas where task-specific lighting levels should be provided include:

a. Designated computer entry and handwritten order-processing locations
b. Pharmacy medication filling and checking
c. Pharmacy patient counseling
d. Sterile compounding and preparation
e. Storeroom for pharmacy medication
f. Medication preparation areas
g. Medication administration work areas, including the patient room

A2.1-2.8.8.1 (2)(e) Height of sharps containers. The National Institute for Occupational Safety and Health (NIOSH) provides an ergonomically ideal formula for determining the height of sharps containers by establishing the eye-level height and maximum thumb tip reach of the worker population and then adding a drop angle of 15 degrees. For a standing workstation, the sharps container height should be 52 to 56 inches (1.32 to 1.42 meters) above the standing surface of the user. For a seated workstation, the sharps container height should be 38 to 42 inches (.97 to 1.07 meters) above the floor on which the chair rests. These height installation recommendations will comfortably accommodate 95 percent of adult female workers. This information can be found in U.S. Department of Health and Human Services (NIOSH) Publication No. 97-111, "Selecting, Evaluating, and Using Sharps Disposal Containers."

A2.1-2.8.8.2 Drug and needle controls. The operational procedures associated with drug and needle controls should be described in the functional program. Such controls may require physical environment components such as electronic surveillance, password-controlled access, and view panels in doors.

2.1-2.8.9.1 Location. Patient nourishment facilities shall be permitted to be located in either an area or a room.

2.1-2.8.9.2 Features. The nourishment area or room shall have the following:

(1) Handwashing station
(2) Work counter
(3) Refrigerator
(4) Microwave
(5) Storage cabinets
(6) Space for temporary storage of food service implements

2.1-2.8.9.3 Unused meal trays. Provisions and space for separate temporary storage of unused meal trays shall be provided.

***2.1-2.8.9.4 Soiled meal trays.** Provisions and/or space for soiled meal trays shall be provided.

*2.1-2.8.10 Ice-Making Equipment

2.1-2.8.10.1 In public areas, all ice-making equipment shall be of the self-dispensing type.

2.1-2.8.10.2 In areas restricted to staff only, use of storage bin-type equipment for making and dispensing ice shall be permitted.

2.1-2.8.11 Clean Workroom or Clean Supply Room

2.1-2.8.11.1 General. The clean workroom or clean supply room shall be separate from and have no direct connection with the soiled workroom or soiled holding room.

2.1-2.8.11.2 Clean workroom. Where the room is used for preparing patient care items, it shall contain the following:

(1) Work counter
(2) Handwashing station
(3) Storage facilities for clean and sterile supplies

2.1-2.8.11.3 Clean supply room. A room used only for storage and holding as part of a system for distribution of clean and sterile supplies does not require a work counter or a handwashing station.

*2.1-2.8.12 Soiled Workroom or Soiled Holding Room

2.1-2.8.12.1 General. Soiled workrooms and soiled holding rooms shall be separate from and have no direct connection with either clean workrooms or clean supply rooms.

2.1-2.8.12.2 Soiled workroom

(1) This room shall contain the following:

(a) Handwashing station
(b) Flushing-rim clinical service sink with a bedpan-rinsing device or equivalent flushing-rim fixture
(c) Work counter
(d) Space for separate covered containers for waste and soiled linen

APPENDIX

A2.1-2.8.9.4 Soiled meal trays. This can be achieved in different ways (e.g., physical separation, enclosed space, and/or dedicated spaces).

A2.1-2.8.10 Ice-making equipment

a. *Noise mitigation.* The location of and space for ice-making equipment in a patient care unit should be designed to mitigate noise. This can be achieved through various means, including considering its placement in relation to patient rooms or locating it in an enclosed space. See Table 1.2-6 (Design Criteria for Minimum Sound Isolation Performance Between Enclosed Rooms) for information about sound for patient rooms.
b. *Biofilm growth prevention.* Consider the configuration of the supply water line and compressor exhaust to prevent the line from heating to a temperature that would promote biofilm growth. Ventilation of the exhaust may be one strategy to prevent heating the supply line.

A2.1-2.8.12 Functions for soiled workroom and soiled holding room

a. *Soiled workroom.* Soiled items may be handled in a soiled workroom to prepare them for subsequent cleaning, disposal, or reuse (e.g., emptying and rinsing bedpans or emesis basins, emptying or solidifying suction canisters, rinsing and gross cleaning of medical instruments). As well, this room provides temporary storage for soiled items prior to their removal from the unit.
b. *Soiled holding room.* This location is used exclusively for temporary storage of soiled materials and/or supplies prior to their removal from the unit.

(2) Where a fluid waste management system is used, the following shall be provided:

(a) Electrical and plumbing connections that meet manufacturer requirements
(b) Space for the docking station

2.1-2.8.12.3 Soiled holding room. This room shall contain the following:

(1) Handwashing station or hand sanitation dispenser
(2) Space for separate covered containers for waste and soiled linen

2.1-2.8.13 Equipment and Supply Storage

2.1-2.8.13.1 Clean linen storage. This storage shall meet the following requirements:

(1) Clean linen shall be permitted to be stored in the clean workroom or clean supply room, in a separate closet, or using a covered cart distribution system on each floor.
(2) Where a covered cart distribution system is used, storage of clean linen carts in a corridor alcove shall be permitted.

***2.1-2.8.13.2 Equipment and supply storage room or alcove.** A room or alcove—sized to provide a minimum of 10 square feet (0.93 square meter) per patient bed—shall be provided on the patient care unit floor for storage of equipment and supplies necessary for patient care.

2.1-2.8.13.3 Storage space for gurneys, stretchers, and wheelchairs. Storage space for gurneys, stretchers, and wheelchairs shall be provided.

***2.1-2.8.13.4 Emergency equipment storage**

(1) Each patient care unit shall have at least one emergency equipment storage location.
(2) Emergency equipment storage shall be provided under visual observation of staff.
(3) Emergency equipment storage locations in corridors shall not encroach on the minimum required corridor width.

2.1-2.8.14 Environmental Services Room

2.1-2.8.14.1 General

(1) Application. One environmental services room shall be permitted to serve more than one patient care unit on a floor.
*(2) Location. An environmental services room shall be readily accessible to the unit or floor it serves.

***2.1-2.8.14.2 Environmental services room features.** Each environmental services room shall be provided with the following:

(1) Service sink or floor-mounted mop sink

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A2.1-2.8.13.2 A health care organization should consider providing a dedicated alcove or storage space adjacent to the outside of the patient room door for personal protective equipment (PPE) needed for transmission-based precautions per the facility's infection prevention protocols.

A2.1-2.8.13.4 Emergency equipment storage. Emergency equipment can be positioned in an alcove located in a corridor. Types of emergency equipment stored include cardiopulmonary resuscitation (CPR) carts, pumps, ventilators, patient monitoring equipment, and portable X-ray units.

a. Emergency power outlets for battery charging should be provided at each emergency equipment location.
b. Needed emergency equipment storage locations and types should be identified in the functional program.

A2.1-2.8.14.1 (2) Environmental services room. Some departments or areas may need individually assigned environmental services rooms. Examples include:

a. Patient care units
b. Clinical areas (e.g., pre- and post-procedure patient care areas, exam rooms, blood draw areas, dialysis treatment areas, infusion areas, and other areas likely to come into contact with blood or body fluids)
c. Sterile areas (e.g., operating rooms, corridors in the semi-restricted area of the surgery suite, sterile labs, and sterile storage)
d. Endoscopy services rooms (e.g., endoscopy procedure room, endoscope processing room)
e. Public and administrative areas (waiting areas, offices, hallways)
f. Compounding pharmacy

A2.1-2.8.14.2 Environmental services room features

a. Environmental services rooms should be planned to accommodate carts used in the housekeeping process.
b. A storage or bin space should be included for recyclable materials: white paper, mixed paper, cans, bottles, and cardboard.

(2) Provisions for storage of supplies and housekeeping equipment
(3) Handwashing station or hand sanitation dispenser

*2.1-2.9 Support Areas for Staff

2.1-2.9.1 Staff Lounge Facilities

Lounge facilities of no less than 100 square feet (9.29 square meters) shall be provided.

2.1-2.9.2 Staff Toilet Room

2.1-2.9.2.1 A staff toilet room shall be readily accessible to each patient care unit.

2.1-2.9.2.2 Each staff toilet room shall contain a toilet and a handwashing station.

2.1-2.9.2.3 Staff toilet rooms shall be permitted to be unisex.

2.1-2.9.3 Storage for Staff

2.1-2.9.3.1 Securable closets or cabinet compartments for the personal articles of staff shall be located in or near the nurse station. At minimum, they shall be large enough for purses and billfolds.

2.1-2.9.3.2 If coat storage is provided, storage of coats in closets or cabinets on each floor or in a central staff locker area shall be permitted.

2.1-2.10 Support Areas for Families, Patients, and/or Visitors

2.1-2.10.1 Family and Visitor Lounge

Each patient care unit shall provide access to a lounge for family and visitors.

2.1-2.10.1.1 Size

(1) The size of this lounge shall be defined in the functional program, but shall accommodate, at minimum, three chairs and one wheelchair space.
(2) In the absence of a functional program, the lounge shall be sized to accommodate at least 1.5 persons for every adult intensive care bed and one person for every four medical/surgical beds in the unit.

2.1-2.10.1.2 This lounge shall be immediately accessible to the patient care unit served.

2.1-2.10.1.3 This lounge shall be permitted to serve more than one patient care unit.

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A2.1-2.9 Support areas for staff

a. *Location.* Support areas for staff should be restricted from public access as defined *Security Design Guidelines for Healthcare Facilities*, Section 02: Buildings and the Internal Environment, published by the International Association for Healthcare Security & Safety. Wherever possible, staff lounge facilities should have access to daylight and views of the outdoors.

b. *Staff rest areas.* Staff rest areas should be provided for every unit that has overnight patient care activities. These rest areas should be readily accessible to the work unit and independent from staff on-call rooms.

As described in the Joint Commission *Sentinel Event Alert*, Issue 48, "Health Care Worker Fatigue and Patient Safety," a substantial number of studies show that worker fatigue "increases the risk of adverse events, compromises patient safety and increases risk to personal safety and well-being."

The Veterans Health Administration (VHA) has demonstrated that conveniently located "napping rooms" lead to less staff fatigue and better performance; see the profile "Conveniently Located 'Napping Rooms' Provide Opportunity for Night- and Extended-Shift Providers to Rest, Leading to Less Fatigue and Better Performance" on the Health Care Innovations Exchange page of the Agency for Healthcare Research and Quality website.

Some suggested nap room features used by the VHA and others include:

—Carpeting for noise control
—A single residential bed
—Storage space for linens
—Window treatments to block exterior light where windows are provided
—Security with door lock for the sleeper
—Communication means to reach the sleeper
—Bright lighting with timer to facilitate wake-up
—Acoustic features, including sound-absorbing ceiling tiles and a sound-masking system to control background noise levels and cover noise. For relevant information about acoustics, see the following tables in this document:
- Table 1.2-4 (Minimum Design Room-Average Sound Absorption Coefficients)
- Table 1.2-5 (Maximum Design Criteria for Noise in Interior Spaces Caused by Building Systems)
- Table 1.2-6 (Design Criteria for Minimum Sound Isolation Performance Between Enclosed Rooms)

Table 2.1-1

Electrical Receptacles for Patient Care Areas in Hospitals

Section	Location	Minimum Number of Single Receptacles[1]	Receptacle Locations[2]
PATIENT BED LOCATIONS			
2.1-2.4.2	Airborne infection isolation (AII) room[3]	12	Devices shall be located to support clinical functions and patient and visitor needs.[4]
2.2-2.2.2	Medical/surgical unit patient room[3]		
2.2-2.2.4.4	Protective environment room[3]		
2.2-2.5.2	Intermediate care unit patient room		
2.2-2.10.2.2	Postpartum unit patient room[3]		
2.2-2.12.2	Pediatric and adolescent unit patient room[3]		
2.6-2.2.2	Rehabilitation unit patient room		
2.2-2.6.2	Intensive care unit (ICU) patient care station	16	Devices shall be located to support clinical functions and patient and visitor needs.[4]
2.2-2.7.2	Pediatric intensive care unit (PICU) patient room		
2.2-2.9.2	Neonatal intensive care unit (NICU) infant care station		
2.2-2.10.3	Labor/delivery/recovery (LDR) and Labor/delivery/recovery/postpartum (LDRP) room		8 convenient to head of mother's bed 4 convenient to each bassinet with one on each wall
2.2-2.16.2	Hospice and/or palliative care room		Convenient to head of bed with one on each wall
2.2-2.11.3.1	Newborn nursery infant care station	4	Convenient to each bassinet
2.2-2.11.3.2	Continuing care nursery infant care station	5	Convenient to head of each bed, crib, or bassinet (At least 50% of these outlets shall be connected to emergency system power and be so labeled.)
2.5-2.2.2	Behavioral and mental health patient care unit patient bedroom	No minimum	

Table 2.1-1 (*continued*)

Electrical Receptacles for Patient Care Areas in Hospitals

Section	Location	Minimum Number of Single Receptacles[1]	Receptacle Locations[2]
DIAGNOSTIC AND TREATMENT AREAS			
2.1-3.2 2.2-3.5.2.1 (2)	Exam room Class 1 imaging room	8	4 convenient to head of gurney or bed or on each lateral side of the imaging gantry
2.2-2.10.11.1	Cesarean delivery room	30[5]	16 convenient to table placement 2 on each wall 6 in the infant care area
2.2-3.1.2.6	Treatment room for basic emergency services	12	Convenient to head of gurney or bed
2.2-3.1.3.3 (2)	Triage room or area in the emergency department	6	Convenient to head of gurney or bed (At least 50% of these receptacles shall be connected to emergency system power and be so labeled.)
2.2-3.1.3.6 (1)	Emergency department treatment room	12	Convenient to head of gurney or bed
2.2-3.1.3.6 (2)	Trauma/resuscitation room	16	Convenient to head of gurney or bed
2.2-3.1.3.6 (6)	Low-acuity patient treatment station	4	Convenient to patient chair
2.2-3.1.3.6 (7)(a)	Interior human decontamination room	4	—
2.2-3.3.2	Observation unit patient care station	8	4 convenient to head of gurney or bed
2.2-3.4.2 2.2-3.5.2.1 (2)	Procedure room (including endoscopy) Class 2 imaging room	12[5]	8 convenient to table placement with at least one on each wall
2.2-3.4.3 2.2-3.5.2.1 (3)	Operating room Class 3 imaging room	36[5]	16 convenient to table placement 2 on each wall
2.2-3.10.2	Hemodialysis patient care stations	8	4 on each side of a patient bed or lounge chair. (Two on each side of the bed shall be connected to emergency power.)
POST-ANESTHESIA CARE LOCATIONS			
2.1-3.4.4	Phase I post-anesthetic care unit (PACU) patient care station	8	Convenient to head of gurney or bed
2.1-3.4.5	Phase II recovery patient care station	4	Convenient to gurney, lounge chair, or bed

[1] Permanently installed single, duplex, or fourplex receptacles or a combination of these shall be permitted. Receptacles in relocatable power taps or mounted on portable equipment shall not be counted as part of the total minimum requirement.

[2]"Convenient" in this table means the cords from the equipment to be used in the room can reach the receptacles without causing a trip hazard.

[3]Omission of receptacles from exterior walls in patient rooms shall be permitted where construction or room configuration makes installation impractical.

[4]The number of receptacles at the patient bed location for these spaces is intended to agree with the number required in the governing edition of NFPA 99: Health Care Facilities Code and NFPA 70: National Electric Code. Additional receptacles shall be provided to support clinical functions and the personal needs of the patient and visitors.

[5]The number of receptacles for these spaces is intended to agree with the number required in the governing edition of NFPA 99: Health Care Facilities Code.

Notes

1. In case of a single transfer switch failure, consideration shall be given to providing some receptacles on critical branch power and some on normal power or to providing two separate sources of critical branch power originating from two different transfer switches at the head of patient beds and in operating rooms, cesarean delivery rooms, and trauma/resuscitation rooms. The number of circuits provided shall comply with NFPA 70 and NFPA 99 requirements.
2. Each patient bed location or procedure room shall be supplied by at least two branch circuits, one from the critical branch system and one or more from the normal system. Critical care locations served from two separate transfer switches on the essential electrical system shall not be required to have separate circuits from the normal system.
3. Branch circuits serving only special purpose receptacles or equipment in critical care areas shall be permitted to be served by other panelboards.
4. An additional receptacle shall be provided for a television if one is furnished in the room.
5. A minimum of one dedicated circuit shall be provided to each critical care patient location.
6. Open heart post-anesthesia recovery spaces require more receptacles than those specified in this table; the number should be determined during the planning phase.
7. Receptacles shall be located so they are not in conflict with suction slides and canisters.

Table 2.1-2

Locations for Nurse Call Devices in Hospitals*

Section	Location	Patient Station	Bath Station	Emergency Call Station	Nurse Master Station	Notes
PATIENT CARE UNITS						
2.1-2.2.6	Patient toilet room		●			2
2.2-2.2.2	Medical/surgical unit patient bed	●		●		1, 2, 3
2.2-2.6.2	Intensive care unit (ICU) patient care station	●		●		1, 2
2.2-2.9.2	Neonatal intensive care unit (NICU) infant care station	●		●		4
2.2-2.10.3	Labor/delivery/recovery (LDR) and Labor/delivery/recovery/postpartum (LDRP) room	●		●		1, 2, 3
2.2-2.11.3.1	Newborn nursery			●		
2.2-2.11.3.2	Continuing care nursery			●		
2.2-2.16.2	Hospice and/or palliative care room	●		●		1, 2, 3
2.5-2.4.2	Alzheimer's and other dementia unit patient bedroom	●				
SUPPORT AREAS						
2.1-2.8.2	Nurse/control station				●	
DIAGNOSTIC AND TREATMENT AREAS						
2.1-2.4.3	Seclusion room anteroom			●		
2.1-3.2	Exam room			●		
2.2-3.5.2.1 (2)	Class 1 imaging room			●		
2.1-3.4.3	Pre-procedure patient care room or area	●		●		1, 2
2.1-3.4.4	Phase I post-anesthetic care unit (PACU) patient care station			●		2
2.1-3.4.5	Phase II recovery patient care station	●		●		1, 2
2.2-2.10.11.1	Cesarean delivery room			●		2
2.2-3.1.3.3 (2)	Triage room or area in the emergency department	●				1, 2

Table 2.1-2 (*continued*)

Locations for Nurse Call Devices in Hospitals*

Section	Location	Patient Station	Bath Station	Emergency Call Station	Nurse Master Station	Notes
2.2-3.1.3.6 (1)	Emergency department treatment room	●				1, 2
2.2-3.1.3.6 (6)	Low-acuity patient care station	●				
2.2-3.1.3.6 (7)(a)	Interior human decontamination room	●		●		1
2.2-3.3.2	Observation unit patient care station			●		
2.2-3.4.2	Procedure room (including endoscopy)			●		2
2.2-3.5.2.1 (2)	Class 2 imaging room			●		2
2.2-3.4.3	Operating room			●		2
2.2-3.5.2.1 (3)	Class 3 imaging room			●		2
2.5-3.4.2.2 (2)	Electroconvulsive therapy (ECT) treatment room			●		2
2.5-3.4.2.3 (2)	ECT pre-treatment patient care area			●		2
2.5-3.4.2.3 (3)	ECT recovery patient care station			●		2

*These devices are listed in UL 1069: *Standard for Hospital Signaling and Nurse Call Equipment.*

Notes

1. One device shall be permitted to accommodate patient station and emergency call station functions.
2. A visible signal shall be activated in the corridor at the patient's door, at the nurse/control station, and at all duty stations. In multi-corridor patient care units, additional visible signals shall be installed at corridor intersections.
3. Two-way voice communication shall be provided with the nurse/control station.
4. The patient station requirement applies only to private NICU rooms.

Table 2.1-3

Oxygen, Vacuum, Medical Air, WAGD, and Instrument Air Systems (Outlets/Inlets)[1]

Section	Location	Oxygen	Vacuum	Medical Air	WAGD[2]	Instrument Air
PATIENT CARE UNITS						
2.1-2.4.2	Airborne infection isolation (AII) room	1/bed	1/bed	—	—	—
2.2-2.2.2	Medical/surgical unit patient room	1/bed	1/bed	—[3]	—	—
2.2-2.2.4.4	Protective environment room	1/bed	1/bed	—	—	—
2.2-2.5.2	Intermediate care unit patient room	2/bed	2/bed	1/bed	—	—
2.2-2.6.2	Intensive care unit (ICU) patient care station	3/bed	3/bed	1/bed	—	—
2.2-2.6.4.2	Airborne infection isolation (intensive care)					
2.2-2.7.2	Pediatric intensive care unit (PICU) room					
2.2-2.9.2	Neonatal intensive care unit (NICU) infant care station	3/infant care bed	3/infant care bed	3/infant care bed	—	—
2.2-2.10.2	Antepartum and postpartum unit	1/bed	1/bed	—	—	—
2.2-2.10.3	Labor/delivery/recovery (LDR)					
2.2-2.10.3	Labor/delivery/recovery/postpartum (LDRP)					
2.2-2.10.3.9	Infant resuscitation space[4] (LDR/LDRP)	1/bassinet	1/bassinet	1/bassinet	—	—
2.2-2.10.11.1	Cesarean delivery room	2/room	4/room	1/room	1/room	—
2.2-2.10.11.1	Infant resuscitation space[4] (cesarean delivery)	3/bassinet	3/bassinet	3/bassinet	—	—
2.2-2.10.11.11	Recovery space for cesarean delivery	1/bed	3/bed	1/bed	—	—
2.2-2.11.3.1	Newborn nursery	1/bassinet[5]	1/bassinet[5]	1/bassinet[5]	—	—
2.2-2.11.3.2	Continuing care nursery	1/bassinet	1/bassinet	1/bassinet	—	—
2.2-2.12.2	Pediatric and adolescent patient room	1/bed	1/bed	1/bed	—	—
2.2-2.16.2	Hospice and/or palliative care room	1/bed[6]	1/bed[6]	1/bed[6]	—	—

Table 2.1-3 (*continued*)

Oxygen, Vacuum, Medical Air, WAGD, and Instrument Air Systems (Outlets/Inlets)[1]

Section	Location	Oxygen	Vacuum	Medical Air	WAGD[2]	Instrument Air
DIAGNOSTIC AND TREATMENT LOCATIONS						
2.1-3.2	Exam room	1/room	1/room	—	—	—
2.1-3.4.4	Phase I post-anesthetic care unit (PACU) patient care station	2/station	3/station	1/station	—	—
2.1-3.4.5	Phase II recovery patient care station	1/station	1/station[7]	—	—	—
2.2-3.1.2.6	Treatment room for basic emergency services	1/gurney	1/gurney	—	—	—
2.2-3.1.3.3 (2)	Triage room or area in the emergency department	1/station	1/station	—[8]	—	—
2.2-3.1.3.6 (1)	Emergency department treatment room or area	1/gurney	1/gurney	1/gurney	—	—
2.2-3.1.3.6 (2)	Trauma/resuscitation room	2/gurney	3/gurney	1/gurney	—	—
	Plaster and cast room	1/room	1/room	—	—	—
2.2-3.1.3.6 (6)	Low-acuity patient care station	—[8]	—[8]	—	—	—
2.2-3.1.3.6 (7) (a)	Interior human decontamination room	1[6]	—[1,9]	—	—	—
2.2-3.3.2	Observation unit patient care station	1/station	1/station	—	—	—
2.2-3.5.2.1 (2)	Class 1 imaging room	1/room	1/room	—	—	—
2.2-3.4.2 2.2-3.5.2.1 (2)	Procedure room Class 2 imaging room	2/room	2/room	1/room	—	—
2.2-3.4.3 2.2-3.5.2.1 (3)	Operating room Class 3 imaging room	2/room	5/room	1/room	1/room	—
2.2-3.11.2	Endoscopy procedure room	1	3	—	—	—
2.2-3.11.3	Endoscopy pre- and post-procedure patient care area	—[8]	—[8]	—	—	—
2.2-3.13.4	Hyperbaric suite pre-procedure patient care area	2	2	—	—	—

Table 2.1-3 (*continued*)

Oxygen, Vacuum, Medical Air, WAGD, and Instrument Air Systems[1] (Outlets/Inlets)

Section	Location	Oxygen	Vacuum	Medical Air	WAGD[2]	Instrument Air
2.5-3.4.2.2 (2)	Electroconvulsive therapy (ECT) treatment room	1[6]	1[6]	—	—	—
GENERAL SUPPORT FACILITIES						
2.1-5.1.2.2 (2)	Two-room sterile processing: Decontamination room	—	—	—	—	1[6,10,11]
2.1-5.1.2.2 (3)	Two-room sterile processing: Clean workroom	—	—	—	—	—[6,10,11]
2.1-5.1.2.3 (2) 2.1-5.1.2.3 (3)	One-room sterile processing: Decontamination area Clean work area	—	—	—	—	—[6,10,11]
2.1-5.7.2.2	Autopsy room	—	1 per workstation	—	—	—
2.2-3.11.4.2	Endoscope processing room decontamination area	—	—	—[12]	—	—[6,11,12]
2.2-3.11.4.3	Endoscope processing room clean work area	—	—	—[12]	—	—[6,11,12]

[1]For any area or room not included in this table the facility clinical staff shall determine station outlet/inlet requirements after consultation with the authority having jurisdiction.

[2]Where inhalation anesthesia is used, a waste anesthesia gas disposal (WAGD) system shall be provided.

[3]Medical air outlets may be required in patient rooms.

[4]When infant resuscitation takes place in a room such as a cesarean delivery room or an LDRP room, infant resuscitation services must be provided in that room in addition to the minimum service required for the mother.

[5]Four bassinets may share one outlet that is accessible to each bassinet.

[6]Use of portable equipment in lieu of a piped gas system shall be permitted.

[7]If the Phase II recovery area is combined with the PACU, three vacuum outlets per bed or station shall be provided.

[8]A portable source shall be available for the space.

[9]Portable vacuum equipment shall be readily accessible.

[10]In the one-room sterile processing facility and the clean workroom of the two-room sterile processing facility, an instrument air outlet or portable compressed air shall be provided as required by the equipment used. In the decontamination room of the two-room sterile processing facility, an instrument air outlet or portable compressed air is required.

[11]NFPA 99 permits the use of portable medical compressed air for single applications. Where cylinders are used for non-respiratory purposes, such as air for blowing down scopes and/or running decontamination equipment, NFPA 99 should be consulted for cylinder air quality, placement, and handling.

[12]Vacuum and/or instrument air shall be provided if needed for the cleaning methods used.

Table 2.1-4

Hot Water Use—General Hospital

	Clinical	Dietary	Laundry
Liters per hour per bed[1]	11.9	7.2	7.6
Gallons per hour per bed[1]	3	2	2
Temperature (°C)	41–49[2]	49[3]	71[4]
Temperature (°F)	105–120[2]	120[3]	160[4]

[1]Quantities indicated for design demand of hot water are for general reference minimums and shall not substitute for accepted engineering design procedures using actual number and types of fixtures to be installed. Design will also be affected by temperatures of cold water used for mixing, length of run and insulation relative to heat loss, etc. As an example, the total quantity of hot water needed will be less when the temperature available at the outlet is very nearly that of the source tank and the cold water used for tempering is relatively warm.

[2]The range represents the maximum and minimum allowable temperatures.

[3]Provisions shall be made to provide 180°F (82°C) rinse water at warewasher (may be by separate booster) unless a chemical rinse is provided.

[4]Provisions shall be made to provide 160°F (71°C) hot water at the laundry equipment when needed. (This may be by steam jet or separate booster heater.) However, it is emphasized that this does not imply that all water used would be at this temperature. Water temperatures required for acceptable laundry results will vary according to type of cycle, time of operation, and formula of soap and bleach as well as type and degree of soil. Lower temperatures may be adequate for most procedures in many facilities, but the higher 160°F (71°C) should be available when needed for special conditions.

Appendix Table A2.1-a

Maximum Length of Hot Water System Pipe or Tube

Nominal Pipe Size (in.)	Liquid Ounces per Foot of Length	Maximum Pipe or Tube Length (ft.)		
		System without Circulation Loop or Heat Traced Line	System with Circulation Loop or Heat Traced Line	Public Handwashing Station Faucets (metering and non-metering)
–	0.33	25	16	6
5/16	0.5	25	16	4
3/8	0.75	25	16	3
1/2	1.5	25	16	2
5/8	2	25	12	1
3/4	3	21	8	0.5
7/8	4	16	6	0.5
1	5	13	5	0.5
1 1/4	8	8	3	0.5