



**and**

**Orthopaedic Surgery Center of Raleigh, LLC**

**Comments on WakeMed's Certificate of Need  
Application to Develop an Additional Operating  
Room at WakeMed North, Project ID # J-12114-21**

**October 1, 2021**

**Comments on WakeMed’s Competing Application to Develop an  
Additional Operating Room at WakeMed North in Wake County**

*submitted by*

**Rex Hospital, Inc. and Orthopaedic Surgery Center of Raleigh, LLC**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. d/b/a UNC REX Hospital and Orthopaedic Surgery Center of Raleigh, LLC (OSCR) (collectively for purposes of these comments, UNC REX) hereby submit the following comments related to the application filed by WakeMed to develop an additional operating room at WakeMed North in Wake County pursuant to the need identified in the *2021 State Medical Facilities Plan (2021 SMFP)* for three additional operating rooms in Wake County. UNC REX’s comments include “*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*<sup>1</sup>.” See N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency’s review of these comments, UNC REX has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to WakeMed’s WakeMed North application, Project ID # F-12114-21.

UNC REX’s detailed comments include not only issue-specific comments on the application noted above, but also a comparative analysis which includes discussion of the WakeMed North application as well as the complementary UNC REX applications noted below:

- **Orthopaedic Surgery Center of Raleigh (OSCR)<sup>2</sup>, Project ID # J-12119-21** (proposal to develop no more than one operating room pursuant to the need determination in the *2021 SMFP* for a total of four operating rooms<sup>3</sup>)
- **Rex Hospital (UNC REX Hospital), Project ID # J-12122-21** (proposal to develop two operating rooms pursuant to the need determination in the *2021 SMFP*)

As detailed above, these comments include a review of a mix of proposals for hospital-based operating rooms and an ambulatory surgical facility (ASF). Moreover, given the number of applications and proposed operating rooms discussed in these comments, all the applications cannot be approved.

UNC REX has a long-standing, demonstrated commitment to developing projects that increase geographic and financial access to healthcare services, feature physician collaboration, and provide cost effective and efficient options for patient care and is committed to the proposals detailed in its applications. The UNC REX applications are the result of prudent healthcare planning to balance the need for hospital-based and

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<sup>1</sup> UNC REX is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the applications filed on August 16, 2021 by UNC REX Hospital (Project ID # J-12122-21) or OSCR (Project ID # J-12119-21).

<sup>2</sup> As noted in the application, OSCR is a joint venture between Raleigh Orthopaedic Clinic, PA (ROC) physicians and UNC REX Healthcare (UNC REX).

<sup>3</sup> Please note that the CON Application Log incorrectly identifies the total number of operating rooms upon project completion as three.

freestanding ASF operating room capacity in Wake County, while increasing geographic access to surgery services.

**ISSUE-SPECIFIC COMMENTS ON WAKEMED NORTH HOSPITAL**

1. The WakeMed North application provides unreasonable utilization assumptions.

In Section Q, WakeMed provides its methodology for projecting utilization for the proposed project and for some of the other facilities in its system. In Step 4 of its methodology (see pages 157 and 158 of the WakeMed North application), WakeMed states that it projects to shift cases from various existing facilities to its approved ASFs in Cary and North Raleigh and provides the number of cases it projects to shift. The application fails completely to provide any methodology or rationale for the projected shifts, however; as such, they cannot be determined to be reasonable. Without any methodology or explanation, the case volume for these facilities cannot be relied upon to demonstrate conformity with the operating room rules.

In Step 8 (see pages 162-167 of the WakeMed North application), WakeMed projects the overall WakeMed system operating room need. At the outset, it is important to note that **WakeMed overstates the overall WakeMed system deficit of operating rooms in its WakeMed North application.** The table below summarizes the projected operating room surplus or deficit as presented by WakeMed on pages 163 through 167 of its WakeMed North application. As calculated by WakeMed in its summary table presented on page 167, the WakeMed system shows an overall system deficit of 7.74 operating rooms in the third full fiscal year of the WakeMed North project (Fiscal Year (FY) 2026). However, as discussed below, **the WakeMed North application contains numerous inconsistencies and mathematical errors, which effectively overstate the overall WakeMed system deficit.**

	<i>Projected OR Deficit / (Surplus) FY 2026 WakeMed North</i>
WakeMed North	0.36
WakeMed Raleigh	3.66
WakeMed Cary	(1.67)
Capital City Surgery Center	(0.60)
WakeMed Surgery Center-North Raleigh	0.64
WakeMed Surgery Center-Cary	0.42
<b>WakeMed System Total</b>	<b>7.74</b>

Source: WakeMed North application.

The table above reflects the overall WakeMed system deficit as calculated by WakeMed on page 167 of its WakeMed North application, while the facility surplus or deficit reflects the individual facility surplus or deficit calculated by WakeMed on pages 163 through 166 of its WakeMed North application.

Of note, the data provided by WakeMed in its summary table presented on page 167 of the WakeMed North application does not match the individual facility deficit calculated by WakeMed on page 163 of its WakeMed North application. In its summary table on page 167, WakeMed incorrectly states the deficit at WakeMed North and WakeMed Raleigh. That is, in Table Q.24 of the WakeMed North application (page 167), WakeMed identifies the deficits as 0.84 and 4.10 for WakeMed North and WakeMed Raleigh, respectively, while in tables Q.17 and Q.18 of the

WakeMed North application (page 163), WakeMed identifies the deficits as 0.36 and 3.66 for WakeMed North and WakeMed Raleigh, respectively.

Further, the data provided by WakeMed in its summary table presented on page 167 of its WakeMed North application is not summed correctly. WakeMed appears to have calculated its system total incorrectly by double counting WakeMed North and WakeMed Raleigh (accounting for them each individually and together under the same license).

As illustrated in the table below, if WakeMed had correctly identified the deficit at WakeMed North and WakeMed Raleigh (discussed above) and correctly summed its projected surpluses or deficits in its summary table on page 167 of the WakeMed North application, WakeMed would show an overall system deficit of 2.81 operating rooms in FY 2026 (as opposed to an overall deficit of 7.74 as calculated by WakeMed on page 167). Given that the summary table on page 167 identifies the deficits at WakeMed North and WakeMed Raleigh individually (incorrectly as 0.84 and 4.10, respectively) and as a license (correctly as 4.02) and the fact that the difference between the deficit calculated by WakeMed (7.74) and the number re-calculated using WakeMed’s incorrectly identified deficits for WakeMed North and WakeMed Raleigh ( $3.73 = 0.84 + 4.10 - 1.67 - 0.60 + 0.64 + 0.42$ ) is roughly the combined deficit under the WakeMed license ( $7.74 - 3.73 = 4.01$ ), it appears that WakeMed incorrectly double counted these facilities in its summary table on page 167 of the WakeMed North application.

	<i>Projected OR Deficit / (Surplus) FY 2026 WakeMed North*</i>	<i>Projected OR Deficit / (Surplus) FY 2026 Corrected</i>
WakeMed North	0.36	0.36
WakeMed Raleigh	3.66	3.66
WakeMed Cary	(1.67)	(1.67)
Capital City Surgery Center	(0.60)	(0.60)
WakeMed Surgery Center-North Raleigh	0.64	0.64
WakeMed Surgery Center-Cary	0.42	0.42
<b>WakeMed System Total</b>	<b>7.74</b>	<b>2.81</b>

\*This column reflects the overall WakeMed system deficit as calculated by WakeMed on page 167 of its WakeMed North application, while the facility surplus or deficit reflects the individual facility surplus or deficit calculated by WakeMed on pages 163 through 166 of its WakeMed North application.

In addition, **WakeMed also fails to account for a related entity – Holly Springs Surgery Center – in calculating the overall WakeMed system deficit of operating rooms and as such, even further overstates the overall WakeMed system deficit of operating rooms in its WakeMed North application.**

As defined in the definition portion of the Certificate of Need application form, when used in the application form, the term “related entity” means a person that:

- Shares the same parent corporation or holding company with the applicant;
- Is a subsidiary of the same parent corporation or holding company as the applicant; or
- **Participates with the applicant in a joint venture that provides the same type of health services proposed in the application.**

**[emphasis added].**

Language in WakeMed’s financial statements, included in Exhibit F-2.3 of its WakeMed North application and excerpted below, suggests that Holly Springs Surgery Center meets the definition of a “related entity” as defined above. In particular, page 33 of WakeMed’s financial statements notes that,

*“[d]uring 2015, **WakeMed formed a joint venture, Holly Springs Surgical Venture, LLC (Holly Springs Surgical Venture), a North Carolina limited liability company, to furnish high-quality surgical services through Holly Spring Surgery Center, LLC (Holly Springs Surgery Center).** The center became operational for patients in February 2017. Specialties, include, but are not limited to, urology, orthopedics, ophthalmology, and spine. The investment is accounted for under the equity method. WakeMed initially owned 42.5 percent of Holly Springs Surgical Venture but increased its ownership percentage to 60.0 percent in February 2019.”*

**[emphasis added].**

Given the language excerpted above from WakeMed’s financial statements, WakeMed should have included Holly Springs Surgery Center in response to 10A NCAC 14C .2103(a) in calculating its projected overall system surplus or deficit and determining whether it meets the applicable performance standard in its WakeMed North application. This is **particularly important to this review as Holly Springs Surgery Center is located in the service area and has a projected surplus of operating rooms.**

As illustrated in the table below, if WakeMed correctly identified the deficit at WakeMed North and WakeMed Raleigh (discussed above), correctly summed its projected surpluses or deficits in its summary table on page 167 of the WakeMed North application (discussed above), and correctly included Holly Springs Surgery Center, it would show an overall system deficit of 1.81 operating rooms in FY 2026 (as opposed to an overall deficit of 7.74 as calculated by WakeMed on page 167 of its WakeMed North application).

	<i>Projected OR Deficit / (Surplus) FY 2026 WakeMed North*</i>	<i>Projected OR Deficit / (Surplus) FY 2026 Corrected**</i>	<i>Projected OR Deficit / (Surplus) FY 2026 Updated^</i>
WakeMed North	0.36	0.36	0.36
WakeMed Raleigh	3.66	3.66	3.66
WakeMed Cary	(1.67)	(1.67)	(1.67)
Capital City Surgery Center	(0.60)	(0.60)	(0.60)
WakeMed Surgery Center-North Raleigh	0.64	0.64	0.64
WakeMed Surgery Center-Cary	0.42	0.42	0.42
Holly Springs Surgery Center			(1.00)
WakeMed System	<b>7.74</b>	<b>2.81</b>	<b>1.81</b>

\*This column reflects the overall WakeMed system deficit as calculated by WakeMed on page 167 of its WakeMed North application, while the facility surplus or deficit reflects the individual facility surplus or deficit calculated by WakeMed on pages 163-166 of its WakeMed North application.

\*\*This column reflects the overall WakeMed system deficit as corrected to account for WakeMed’s inconsistencies and incorrect calculations on page 167 of its WakeMed North application as discussed above.

^This column reflects the overall WakeMed system deficit as corrected in the previous column, which is then updated to account for Holly Springs Surgery Center’s surplus of one operating room as reflected in the *Proposed 2022 SMFP* (which projects the surplus or deficit for 2024).

It is also relevant to review of the WakeMed North application that: (1) according to the *2021 SMFP*, **the WakeMed system has the highest projected operating room surplus of any system in Wake County**; and (2) this surplus is projected to continue according to the *Proposed 2022 SMFP*, which shows that **the WakeMed system is still projected to have the highest projected operating room surplus of any system in Wake County**.

It is also important to note in the review of the WakeMed North application that **WakeMed has taken completely opposite positions regarding its need (or lack thereof) for operating rooms for its WakeMed Raleigh license (which includes WakeMed North and WakeMed Raleigh)**. In Section Q of the WakeMed North application, WakeMed provides its methodology for projecting utilization for its proposed projects and for some of the other facilities in its system. In Step 8, WakeMed projects an overall deficit of four operating rooms relative to its WakeMed Raleigh license in its WakeMed North application (see page 164, which shows a deficit of 4.02 operating rooms). It is relevant to review of the WakeMed North application that **in both its 2019 and 2020 operating room applications WakeMed projected either the same or a larger deficit of operating rooms for its WakeMed Raleigh license than projected in its current application, but nonetheless found its operating room complement sufficient for the WakeMed Raleigh license.** This is illustrated by excerpts from two past applications.

In its 2019 application to develop one additional operating room at WakeMed Cary, Project ID # J-11759-19, notwithstanding the fact that WakeMed projected a deficit of more than five operating rooms at WakeMed’s Raleigh campus (which it noted includes WakeMed North and WakeMed Raleigh), it stated that “[d]espite the calculated deficit of operating rooms for WakeMed Raleigh Campus, WakeMed executive leadership are confident that its current and proposed OR complement will be adequate for the next several years.” See page 124 of WakeMed’s 2019 application, Project ID # J-11759-19 (also noting that

*“WakeMed would not have sought approval to relocate an OR from WakeMed Raleigh to WakeMed Cary (as proposed in Project No. J-11428-17) if WakeMed Raleigh’s OR need were as critical as that calculated in the OR Need Methodology, as shown in Table Q.15”*).

In its 2020 application to develop one additional operating room at WakeMed Cary, Project ID # J-11960-20, notwithstanding the fact that WakeMed projected a deficit of four operating rooms at WakeMed’s Raleigh campus (which it noted includes WakeMed North and WakeMed Raleigh), it stated that “[d]espite the calculated deficit of operating rooms for WakeMed Raleigh Campus shown in Table Q.12, WakeMed’s executive leadership believe that its current OR complement is sufficient.” See page 124 of WakeMed’s 2020 application, Project ID # J-11960-20 (also noting that *“WakeMed would not have sought approval to relocate an OR from WakeMed Raleigh to WakeMed Cary (as proposed in Project No. J-11428-17) if WakeMed Raleigh’s OR need were as critical as that calculated in the OR Need Methodology”*).

Somehow, the WakeMed Raleigh license, with a projected deficit of four operating rooms in its current application needs an additional operating room at WakeMed North, but as stated in WakeMed’s 2019 and 2020 applications, Project ID #s J-11960-20 and J-11759-19, respectively, WakeMed Raleigh license’s purported four and more than five operating room deficits represented “sufficient” capacity. As shown in the table below, when using the case times from the 2019, 2020 and 2021 SMFPs, respectively, as required by the performance standards in the administrative rules, WakeMed has taken completely opposite positions regarding its need (or lack thereof) for operating rooms as it relates to the WakeMed North application and WakeMed’s applications from the past two years.

<b>Application</b>	<b>WakeMed Raleigh License^ Projected OR (Surplus)/Deficit Using Average Case Times Published in the Applicable SMFP</b>	<b>WakeMed Position</b>	<b>Applied for</b>
2019 WakeMed Cary Application, Project ID # J-11759-19 (PY 3 = FY 2023)	5.45 deficit	Deficit of more than five ORs but capacity is sufficient.	One OR at WakeMed Cary, which showed a surplus of four ORs*
2020 WakeMed Cary Application, Project ID # J-11960-20 (PY 3 = FY 2025)	3.87 deficit	Deficit of four ORs but capacity is sufficient.	One OR at WakeMed Cary, which showed a surplus of one OR**
Current WakeMed North Application (PY 3 = FY 2026)	3.71 deficit	Deficit of four ORs means insufficient capacity.	One OR at WakeMed North, which showed a deficit of zero ORs

Source: 2019 WakeMed Cary application, page 125; 2020 WakeMed Cary application, page 126; and WakeMed Raleigh application, page 149.

^Includes WakeMed North and WakeMed Raleigh.

\*As noted on page 122 of the 2019 WakeMed Cary application, “[o]ne OR will be relocated from WakeMed Raleigh to WakeMed Cary, per Project No. J-11428-17, in FY 2020. The proposed project is scheduled to open in FY 2021.”

\*\*As noted on page 123 of the 2020 WakeMed Cary application, “[o]ne OR relocated from WakeMed Raleigh to WakeMed Cary in FY 2020, per Project No. J-11428-17.”



Clearly, this inconsistency is irreconcilable and WakeMed has not demonstrated its projections and proposal in the WakeMed North application to be based on reasonable assumptions.

Based on these issues, WakeMed fails to demonstrate that the WakeMed North project is needed or that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183. As such, **the WakeMed North application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2100 et seq.**

2. The WakeMed North application fails to demonstrate that it has proposed the least costly or most effective alternative.

As discussed above, WakeMed fails to demonstrate that the project is needed under Criterion 3 or that the project is consistent with the review criteria implemented under N.C. Gen. Stat. § 131E-183 and has therefore also failed to demonstrate that its chosen alternative is the least costly or most effective.

In Section E.2, pages 91 through 93, WakeMed discussed several alternatives it considered prior to the submission of its application as proposed. The options WakeMed considered included:

- Maintain the Status Quo;
- Develop an OR with No Additional Support Space;
- Develop Procedure Rooms Only with No Additional OR;
- Develop an Ambulatory Surgical Facility;
- Relocate Existing Operating Room(s) Within the WakeMed System; and,
- Develop One Additional Operating Room at WakeMed North.

In reviewing WakeMed's alternatives, UNC REX believes that WakeMed failed to account for all reasonable alternatives – namely, developing an operating room at WakeMed Surgery Center-North Raleigh. Notably, in Step 5 of its methodology, WakeMed projects a deficit of 0.64 operating rooms at WakeMed Surgery Center-North Raleigh; however, WakeMed is applying to develop one additional operating room at WakeMed North – a hospital location where it projects a deficit of zero operating rooms. By not addressing developing an operating room at WakeMed Surgery Center-North Raleigh in its alternatives, WakeMed failed to adequately demonstrate why developing an operating room at WakeMed Surgery Center-North Raleigh was not an effective alternative – in particular given the fact that somehow, WakeMed North, with a projected deficit of zero operating rooms (as a deficit of 0.36 does not round to one) needs an operating room, but WakeMed's ASF in North Raleigh with a deficit of one operating room represents "sufficient" capacity.

Based on this issue, WakeMed fails to demonstrate that its project as proposed represents the least costly or most effective alternative. As such, **the WakeMed North application should be found non-conforming with Criteria 1, 3, and 4.**

3. The WakeMed North application financials are not based on reasonable or supported assumptions.

As noted above with regard to Criterion 3, the WakeMed North application includes unreasonable and unsupported utilization projections; as such, the projected financials are based on unreasonable and unsupported assumptions. Further, the WakeMed North application does not describe what comprises Indirect Expense (OH/Admin) within Surgical Services or how this expense is allocated to Surgical Services. This is especially important since this expense is the third largest line item expense for the service and is drastically lower than what was projected in WakeMed’s 2019 and 2020 WakeMed Cary applications, Project ID #s J-11759-19 and J-11960-20, respectively, as shown in the table below. Based on prior WakeMed applications and WakeMed’s lack of explanation in its current application, these expenses appear to be understated by as much as \$3 million per year.

	<i>WakeMed North PY 3 = FY 2026</i>	<i>2019 WakeMed Cary* PY 3 = FY 2023</i>	<i>2020 WakeMed Cary** PY 3 = FY 2025</i>
Indirect Expense (OH/Admin) PY 3	\$2,917,364	\$13,221,107	\$12,001,405
% Gross Revenue PY 3	1.1%	2.1%	2.2%
% Net Revenue PY 3	3.9%	9.1%	9.2%
% Total Expenses PY 3	7.2%	20.5%	20.2%
Total # of Surgical Cases PY 3	4,441	9,645	8,802

\*2019 WakeMed Cary Application, Project ID # J-11759-19.

\*\*2020 WakeMed Cary Application, Project ID # J-11960-20.

Further, current staff expense appears to be understated. Notably, while the salary amounts in Form H and Form F.3a match for project years 1 through 3, Form H indicates a projected 2021 staff expense of \$4,064,816 (as of June 30, 2021) compared to a projected 2021 expense of \$3,382,171 in Form F.3a (as of September 30, 2021).

Based on these issues, WakeMed fails to demonstrate that the project is financially feasible based on reasonable and supported assumptions of costs and charges. As such, **the WakeMed North application should be found non-conforming with Criterion 5.**

4. The WakeMed North application cannot be approved as submitted, as it is incomplete and fails to include all information necessary for the Agency to conduct the review pursuant to N.C. GEN. STAT. § 131E-182(b).

Specifically, WakeMed fails to provide all requested information required in response to the CON application form as it fails to identify all related entities in response to Form O Facilities and the performance standards.

As defined in the definition portion of the CON application form, when used in the application form, the term “related entity” means a person that:

- Shares the same parent corporation or holding company with the applicant;

- Is a subsidiary of the same parent corporation or holding company as the applicant; or
- **Participates with the applicant in a joint venture that provides the same type of health services proposed in the application.**

**[emphasis added]**.

As noted previously, language in WakeMed’s financial statements, included in Exhibit F-2.3 of its WakeMed North application and excerpted below, suggests that Holly Springs Surgery Center meets the definition of a “related entity” as defined above. In particular, page 33 of WakeMed’s financial statements notes that,

*“[d]uring 2015, **WakeMed formed a joint venture, Holly Springs Surgical Venture, LLC (Holly Springs Surgical Venture), a North Carolina limited liability company, to furnish high-quality surgical services through Holly Spring Surgery Center, LLC (Holly Springs Surgery Center).** The center became operational for patients in February 2017. Specialties, include, but are not limited to, urology, orthopedics, ophthalmology, and spine. The investment is accounted for under the equity method. WakeMed initially owned 42.5 percent of Holly Springs Surgical Venture but increased its ownership percentage to 60.0 percent in February 2019.”*

**[emphasis added]**.

Given the language excerpted above from WakeMed’s financial statements, WakeMed should have included Holly Springs Surgery Center in response to Form O Facilities. Section O.1 of the CON application form requires an applicant to “[i]dentify all existing and approved facilities providing the same service components included in this proposal **that are owned, operated or managed by the applicant or a related entity** in North Carolina by completing Form O Facilities, which is found in Section Q.” **[emphasis added]**. However, while WakeMed identifies WakeMed Raleigh, WakeMed Cary, Capital City Surgery Center, WakeMed Surgery Center-North Raleigh, and WakeMed Surgery Center-Cary in response to Form O Facilities (see page 176 of the WakeMed North application), it fails to identify a related entity, Holly Springs Surgery Center.<sup>4</sup> As such, the WakeMed North application fails to provide all requested information required in response to the CON application form as it fails to identify all related entities in response to Form O Facilities.

Further, WakeMed should have included Holly Springs Surgery Center in response to 10A NCAC 14C .2103(a) in calculating its projected overall system surplus or deficit and determining whether it meets the applicable performance standard in its WakeMed North application. This is **particularly important to this review as Holly Springs Surgery Center is located in the service area and has a projected surplus of operating rooms**. By failing to include all related entities in calculating the overall WakeMed system deficit of operating rooms, WakeMed even further overstates the overall WakeMed system deficit of operating rooms in its WakeMed North application.

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<sup>4</sup> See article available at: <https://hssurgery.com/articles/holly-springs-surgery-center-completes-first-total-outpatient-knee-replacement-case> (noting that “Holly Springs Surgery Center is an innovative joint venture with WakeMed Health, Novant Health, Compass Surgical Partners and a group of local surgeons.”).

Based on these issues, WakeMed fails to provide information necessary to determine whether the proposed project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and with duly adopted standards, plans, and criteria. As such, **the WakeMed North application should be found non-conforming with Criteria 1, 3, and the performance standards at 10A NCAC 14C .2100 et seq.**

**In summary, WakeMed has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and that the project is needed, and the WakeMed North application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2100 et seq. The WakeMed North application should not be approved.**

## COMPARATIVE ANALYSIS

Given that multiple applicants propose to meet all or part of the need for the three additional operating rooms in Wake County, not all can be approved as proposed. Please note that this comparative analysis includes discussion relative to three applicants in this competitive review – WakeMed North, Project ID # J-12114-21; OSCR, Project ID # J-12119-21; and UNC REX Hospital, Project ID # J-12122-21.<sup>5</sup>

To determine the comparative factors that are applicable in this review, UNC REX examined recent Agency findings for competitive operating room reviews. Based on that examination and the facts and circumstances of the competing applications in this review, UNC REX considered the following factors:

- Conformity with Review Criteria
- Competition
- Historical Utilization
- Geographic Accessibility
- Patient Access to Lower Cost Surgical Services
- Scope of Services/Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Average Revenue per Case
- Projected Average Operating Expense per Case

UNC REX believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

### **Conformity with Applicable Statutory and Regulatory Review Criteria**

As discussed in the application-specific comments above, the WakeMed North application is non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC REX applications are conforming with all applicable statutory and regulatory review criteria. Therefore, of the three applicants discussed in these comments, the UNC REX applications submitted by UNC REX Hospital and OSCR are more effective alternatives with regard to conformity with statutory and regulatory review criteria.

### **Competition**

The following table identifies the adjusted planning inventory of operating rooms for each applicant as a percent of the total existing and approved Wake County operating rooms, based on Table 6B of the *Proposed 2022 SMFP*. Table 6B shows a total of 113 existing and approved operating rooms in Wake County, excluding the need determination for three operating rooms in the *2021 SMFP*.

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<sup>5</sup> Please note that these comments do not address WakeMed’s application to develop an additional operating room at WakeMed Raleigh, Project ID # J-12115-21 or that application’s conformity or non-conformity with the statutory and regulatory review criteria. As such, there is no discussion of the WakeMed Raleigh application in the comparative analysis in these comments.

	<i>Adjusted OR Planning Inventory</i>	<i>Applicants' ORs as a % of Total Wake County ORs</i>
UNC REX Hospital*	27	
Rex Surgery Center of Cary	4	
Rex Surgery Center of Wakefield	2	
Raleigh Orthopedic Surgery Center	3	
Raleigh Orthopedic Surgery Center-West Cary	1	
Orthopedic Surgery Center of Garner	1	
<b>UNC Health System</b>	<b>38</b>	<b>33.6%</b>
WakeMed Raleigh**	22	
WakeMed Cary Hospital	10	
WakeMed Surgery Center-Cary^	1	
WakeMed Surgery Center-North Raleigh	1	
Capital City Surgery Center^	7	
Holly Springs Surgery Center^^	3	
<b>WakeMed System (w/o Holly Springs Surgery Center)</b>	<b>41</b>	<b>36.3%</b>
<b>WakeMed System (w/ Holly Springs Surgery Center)</b>	<b>44</b>	<b>39.0%</b>
<b>Wake County Total</b>	<b>113</b>	

\*Includes UNC Rex Holly Springs Hospital as it is licensed as a part of UNC REX Hospital.

\*\*Includes WakeMed North as it is licensed as a part of the WakeMed Raleigh campus.

^Joint venture between WakeMed and Compass Surgical Partners, LLC.

^^Joint venture between WakeMed, Compass Surgical Partners, LLC, and Novant Health.

As shown in the table above, the WakeMed system controls 36.3 percent of the existing and approved operating rooms in Wake County excluding Holly Springs Surgery Center and 39.0 percent including Holly Springs Surgery Center. UNC Health controls 33.6 percent. Therefore, based on the Agency's past position on this comparative factor – that the expansion of an existing provider that currently controls fewer operating rooms than another provider would represent the most effective alternative – the applications submitted by UNC REX Hospital and OSCR are more effective alternatives than the WakeMed North application with regard to increasing competition for surgical services in Wake County.

## **Historical Utilization**

The following table shows projected operating room surplus or deficit for the existing providers of surgical services in Wake County who have submitted applications in this review. The projected operating room deficits (surplus), from the 2021 SMFP, Table 6B, Projected Operating Room Need for 2023, are based on the historical utilization of existing providers of surgical services in the service area.

**Projected 2023 Operating Room Need for Wake County by Health System**

	<i>Adjusted OR Planning Inventory</i>	<i>Projected OR Deficit / (Surplus) 2023</i>
UNC Health System	37	4.17
WakeMed System	41	(1.50)

\*Source: 2021 SMFP, Table 6B.

As the table above shows, based on the operating room need determination methodology for Wake County in the 2021 SMFP, UNC Health System is projected to have the highest operating room deficit in 2023 and the WakeMed system is projected to have a surplus. Therefore, based on the Agency’s past position on this comparative factor – that applications proposing to develop additional operating rooms in the health systems with the highest projected operating room deficits are the most effective alternatives – the UNC REX applications submitted by UNC REX Hospital and OSCR are more effective proposals than the WakeMed North application with respect to this comparative factor.

## **Geographic Accessibility**

All three applicants discussed in these comments propose adding the operating rooms to an existing facility. Thus, none of the applicants propose to expand geographic accessibility.

## **Patient Access to Lower Cost Surgical Services**

As noted in the 2020 Wake County Operating Review (see Attachment 1), *“many, but not all outpatient surgical services can be appropriately performed either in a hospital licensed operating room (either shared inpatient/outpatient operating rooms or dedicated ambulatory surgery operating rooms) or in a non-hospital licensed operating room at an ambulatory surgery center; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room at an ASC.”* WakeMed North and UNC REX Hospital are existing hospitals with hospital licensed operating rooms. OSCR, proposes to develop an additional non-hospital based licensed operating room in its existing ASF in Raleigh.

The following table identifies the existing and approved inpatient, outpatient, and shared operating rooms in Wake County.

### Operating Rooms by Classification

	<i>Wake County</i>	<i>% of Total</i>
Inpatient Operating Rooms	3	2.7%
Outpatient Operating Rooms*	39	35.1%
Shared Operating Rooms	69	62.2%
<b>Total Operating Rooms</b>	<b>111</b>	<b>100.0%</b>

Source: *Proposed 2022 SMFP*.

\*Adjusted to include three ASF operating rooms in the settlement of the 2020 Wake County operating room review.

The table below shows the percentage of total Wake County surgical cases that were ambulatory cases in FY 2020, based on the data reported in the *Proposed 2022 SMFP*.

### Ambulatory Surgical Cases as Percent of Total Wake County Surgical Cases

	<i>Type</i>	<i>Inpatient Cases</i>	<i>Ambulatory (Outpatient) Cases</i>	<i>Total Cases</i>	<i>Percent Ambulatory</i>
Blue Ridge Surgery Center	ASF	-	4,938	4,938	100%
Raleigh Plastic Surgery	ASF	-	303	303	100%
Raleigh Orthopaedic Surgery	ASF	-	4,126	4,126	100%
Rex Surgery Center of Cary	ASF	-	3,810	3,810	100%
Rex Surgery Center Wakefield	ASF	-	2,325	2,325	100%
UNC REX Hospital	Hospital Shared	7,631	10,839	18,470	59%
Capital City Surgery Center	ASF	-	6,055	6,055	100%
WakeMed Raleigh*	Hospital Shared	7,952	11,194	19,146	58%
WakeMed Cary Hospital	Hospital Shared	2,867	3,681	6,548	56%
Holly Springs Surgery Center	ASF	-	2,266	2,266	100%
Triangle Orthopedic Surgery Center	ASF	-	2,497	2,497	100%
Duke Raleigh Hospital	Hospital Shared	3,369	6,575	9,944	66%
<b>Total</b>		<b>21,819</b>	<b>58,609</b>	<b>80,428</b>	<b>73%</b>

Source: *Proposed 2022 SMFP*.

\*Includes WakeMed North as it is licensed as a part of the WakeMed Raleigh campus.

As illustrated in the table above, 73 percent of Wake County’s FFY 2020 surgical cases were ambulatory surgery cases and the ASF operating rooms represent 35 percent of the total existing and approved Wake County operating rooms. As discussed on page 48 of the UNC REX application to develop two operating rooms at UNC REX Hospital, the need for hospital-based operating rooms in Wake County persists despite the ratio of outpatient to inpatient cases. In some competitive operating room reviews, the Agency has used this ratio to determine that applicants proposing dedicated outpatient operating rooms are more effective. This simple comparison does not consider all of the factors driving the need for hospital-based operating rooms in Wake County. Specifically, cases reported on license renewal applications (LRAs) as “outpatient,” even for hospitals, may have involved an overnight stay or care provided outside of typical business hours. For example, patients at UNC REX that stay in the hospital post-operatively for fewer than two midnights are classified as outpatients, but they are not appropriate for an ASF setting given the need for overnight stays following surgery. While much of the surgical volume that was classified as inpatient



five years ago has been removed from the inpatient only list, such as total joint cases, many of these cases are classified as outpatient, but still require an overnight stay and for a bed to be occupied until the patient can be discharged. As such, these cases are inappropriate for most ASFs. For these reasons, UNC REX continues to believe that this is not an effective comparative factor.

However, based on the Agency’s past position on this comparative factor – that the expansion of ASF operating rooms in a service area where the percentage of ASF operating rooms represents a smaller percentage of the total existing and approved service area operating rooms than hospital-based operating rooms, and the percentage of total surgical cases performed as ambulatory (outpatient) surgeries is greater than the percentage of inpatient surgeries would represent the most effective alternative – the application submitted by OSCR to develop an ASF operating room would represent a more effective alternative if this comparative factor is applied.

**Scope of Services/Patient Access to Surgical Specialties**

One of the three applicants discussed in these comments – OSCR – proposes to develop an additional operating room at an existing ASF. Based on the Agency’s past position on this comparative factor, ASFs, whether single specialty or multispecialty, in general provide access to a lower number of specialties than hospitals. Of the remaining two applicants discussed in these comments, only one – UNC REX Hospital – is a tertiary surgical provider. As such, the UNC REX Hospital application is a more effective alternative than the WakeMed North application with regard to access to surgical specialties.

**Access by Underserved Groups**

The following table shows projected operating room cases to be provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in Section L.3(a) of each application discussed in these comments.

**Self Pay/Indigent/Charity, Medicare, and Medicaid Surgical Cases – Project Year 3**

<i>Applicant</i>	<i>Self Pay/ Indigent/Charity as % of Total</i>	<i>Medicare % of Total</i>	<i>Medicaid % of Total</i>
WakeMed North	3.1%	33.4%	5.6%
UNC REX Hospital	3.1%	40.9%	4.3%
OSCR	1.0%	20.1%	1.4%

Source: Section L.3(a) of the respective applications.

As shown in the table above, relative to the three applicants discussed in these comments, WakeMed North projects the highest percentage of Medicaid patients; however, as noted above, the WakeMed North application does not adequately demonstrate that its proposal is conforming to all applicable statutory and regulatory review criteria. Therefore, while the WakeMed North application would be more effective than the other applications discussed in these comments with regard to Medicaid patients, the WakeMed North application cannot be approved. UNC REX Hospital projects the highest percentage of Medicare patients. As such, the UNC REX Hospital application represents a more effective alternative with regard to this comparative factor.

### **Projected Average Revenue per Case**

The following table shows the projected gross revenue per operating room case in the third year of operation based on the information provided in the pro forma financial statements (Form F.2). The per case expenses below include both operating room cases and procedure room procedures because revenues and expenses for each room type were not provided separately in the WakeMed North application.

<i><b>Applicant</b></i>	<i><b>Cases</b></i>	<i><b>Gross Revenue</b></i>	<i><b>Average Gross Revenue Per Case</b></i>
OSCR	4,336	\$108,999,420	\$25,138
UNC REX Hospital	19,321	\$668,480,841	\$34,599
WakeMed North	5,228	\$274,642,269	\$52,533

Source: Forms C and F.2 of the respective applications.

As shown above, OSCR projects the lowest gross revenue per surgical case in the third operating year. Therefore, the application submitted by OSCR is a more effective with respect to gross revenue per surgical case. Of the two hospital applicants discussed in these comments, UNC REX Hospital's gross charge per case is significantly lower than WakeMed North's. Therefore, the application submitted by UNC REX Hospital is a more effective alternative than the application submitted by WakeMed North.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in the pro forma financial statements (Form F.2). The per case expenses below include both operating room cases and procedure room procedures because revenues and expenses for each room type were not provided separately in the WakeMed North application.

<i><b>Applicant</b></i>	<i><b>Cases</b></i>	<i><b>Net Revenue</b></i>	<i><b>Average Net Revenue Per Case</b></i>
OSCR	4,336	\$21,499,015	\$4,958
UNC REX Hospital	19,321	\$226,972,630	\$11,747
WakeMed North	5,228	\$75,008,160	\$14,347

Source: Forms C and F.2 of the respective applications.

Similar to gross revenue per case, as shown above, OSCR projects the lowest net revenue per surgical case in the third operating year and is a more effective alternative with respect to net revenue per surgical case. Of the two hospital applicants, UNC REX Hospital's net revenue per case is significantly lower than WakeMed North and is a more effective alternative than WakeMed North.

### **Projected Average Operating Expense per Case**

The following table shows the projected average operating expense per case/procedure in the third year of operation for each of the three applicants discussed in these comments, based on the information provided in those applicants' pro forma financial statements (Form F.3). The per case expenses below include both operating room cases and procedure room procedures because revenues and expenses for each room type were not provided separately in the WakeMed North application.

**Operating Expenses per Case – Project Year 3**

<i>Applicant</i>	<i>Cases</i>	<i>Operating Expenses</i>	<i>Average Operating Expense Per Case</i>
OSCR	4,336	\$18,250,375	\$4,209
WakeMed North	5,228	\$40,648,547	\$7,775
UNC REX Hospital	19,321	\$200,739,284	\$10,390

Source: Form C Utilization and Form F.3.

As shown in the table above, OSCR projects the lowest average operating expense per case in the third project year. Therefore, the OSCR application is a more effective alternative with regard to operating expenses. Between the two hospital applicants discussed in these comments, WakeMed North projects the lowest operating expenses per case. However, as noted above, the WakeMed North application does not adequately demonstrate that its proposal is conforming to all applicable statutory and regulatory review criteria. Therefore, while the WakeMed North application would be most effective alternative when compared to UNC REX Hospital with regard to this comparative factor, the WakeMed North application cannot be approved. As such, UNC REX Hospital is a more effective alternative than WakeMed North.

It should be noted that the Agency’s past position on this comparative factor is that the application proposing the lowest average operating expense per surgical case is generally the more effective alternative with regard to this comparative factor, since a lower average may indicate a lower cost to the patient or third-party payer. In this instance, despite a cost advantage, WakeMed North’s net revenue per case is 22 percent higher than UNC REX Hospital’s. The fact that these lower costs do not result in cost savings to the patient or third-party payors is more evidence that UNC REX Hospital is a more effective alternative than WakeMed North.

**SUMMARY**

In summary, among the three applications discussed in these comments, none applied for all three operating rooms. As such, more than one applicant can be approved. UNC REX believes that some of the operating rooms should be approved for a hospital setting, where they can provide care to both inpatients and outpatients, as well as emergency patients, and provide access to more specialties and patients of all acuities. UNC REX also believes that it is important to expand access to lower cost surgical services in an ASF setting. The UNC REX Hospital and OSCR applications are the result of prudent healthcare planning to balance the need for freestanding ASF and hospital-based operating room capacity in Wake County.

To assess the most effective alternatives for these operating rooms, the following table summarizes the comparative analysis shown above compare the OSCR and UNC REX and WakeMed North applications.

<b>Comparative Factor</b>	<b>UNC REX Hospital</b>	<b>OSCR</b>	<b>WakeMed North</b>
Conformity with Applicable Statutory and Regulatory Review Criteria	More Effective	More Effective	Less Effective
Competition	More Effective	More Effective	Less Effective
Historical Utilization	More Effective	More Effective	Less Effective
Geographic Accessibility	NA	NA	NA
Patient Access to Lower Cost Surgical Services	Less Effective	More Effective	Less Effective
Scope of Services	More Effective	Less Effective	Less Effective
Access by Underserved Groups	More Effective	Less Effective	Less Effective
Projected Average Revenue/Case	More Effective	More Effective	Less Effective
Projected Average Operating Expense/Case	More Effective	More Effective	Less Effective

***Please note that in no way does UNC REX intend for these comments to change or amend its applications filed on August 16, 2021. If the Agency considers any of these comments to be amending UNC REX's applications, those responses should not be considered.***

**REQUIRED STATE AGENCY FINDINGS****FINDINGS**

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2021

Findings Date: February 25, 2021

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

**COMPETITIVE REVIEW**


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Project ID #: J-11960-20  
 Facility: WakeMed Cary Hospital  
 FID #: 990332  
 County: Wake  
 Applicant: WakeMed  
 Project: Develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP

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Project ID #: J-11961-20  
 Facility: Valleygate Surgery Center  
 FID #: 200741  
 County: Wake  
 Applicant: Valleygate Surgery Center, LLC  
 Project: Develop a new ASC with no more than 1 operating room and 3 procedure rooms pursuant to the need determination in the 2020 SMFP

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Project ID #: J-11962-20  
 Facility: Orthopaedic Surgery Center of Garner  
 FID #: 200740  
 County: Wake  
 Applicant: Orthopaedic Surgery Center of Garner, LLC  
 Project: Develop a new ASC with no more than 2 operating rooms and 2 procedure rooms pursuant to the need determination in the 2020 SMFP

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Project ID #: J-11963-20  
 Facility: Rex Hospital  
 FID #: 953429  
 County: Wake  
 Applicant: Rex Hospital, Inc.  
 Project: Add no more than 1 operating room pursuant to the need determination in the 2020 SMFP for a total of no more than 32 operating rooms

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Project ID #: J-11966-20  
Facility: Duke Health Garner Ambulatory Surgical Center  
FID #: 200744  
County: Wake  
Applicant: Duke University Health System, Inc.  
Project: Develop a new ASC with no more than 1 operating rooms and 2 procedure rooms pursuant to the need determination in the 2020 SMFP

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Project ID #: J-11967-20  
Facility: Duke Health Green Level Ambulatory Surgical Center  
FID #: 180422  
County: Wake  
Applicant: Duke University Health System, Inc.  
Project: Add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC)

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Each application was reviewed independently (or standing alone) against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After reviewing each application independently, the Healthcare Planning and Certificate of Need Section (CON Section) conducted a comparative analysis of all the applications to aid in determining which applications to approve. The Decision is at the end of these Required State Agency Findings (Findings), after the Comparative Analysis.

### **REVIEW CRITERIA**

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

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

C  
All Applications

### **Need Determination**

The 2020 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional operating rooms in North Carolina by service area. Application of the need methodology in the 2020 SMFP identified a need for three additional operating rooms in the Wake County service area. Six applications were received by the Healthcare Planning and

**Patient Access to Lower Cost Surgical Services**

There are currently 110 existing or approved operating rooms (excluding dedicated C-Section and trauma operating rooms) in the Wake County operating room service area. Operating rooms can be licensed either under a hospital license or an ambulatory surgery center license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be appropriately performed either in a hospital licensed operating room (either shared inpatient/outpatient operating rooms or dedicated ambulatory surgery operating rooms) or in a non-hospital licensed operating room at an ambulatory surgery center; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room at an ASC. Nonetheless, along with inpatient surgical services, there are some outpatient surgical services that must be performed in a hospital setting.

The following table identifies the existing and approved inpatient (IP), outpatient (OP) and shared inpatient/outpatient operating rooms in Wake County.

	<b>Total ORs*</b>	<b>IP ORs</b>	<b>% IP of Total ORs</b>	<b>OP ORs**</b>	<b>% OP of Total ORs</b>	<b>Shared ORs</b>	<b>% Shared of Total ORs</b>
Wake County Operating Rooms	110	3	2.7%	38	34.5%	69	62.7%

Source: 2021 SMFP.

\*Total operating rooms includes existing and approved operating rooms and excludes dedicated C-Section and designated trauma operating rooms.

\*\*Includes two single-specialty demonstration project operating rooms at Triangle Orthopaedics Surgery Center.

The table below shows the percentage of total Wake County surgical cases that were ambulatory surgeries in FY2019, based on data reported in the 2021 SMFP.

**Ambulatory Surgical Cases as Percent of  
 Total Wake County Surgical Cases**

Wake County Surgical Facility	Type of ORs	Inpatient Cases	Ambulatory (Outpatient) Cases	Total Cases	Percent Ambulatory
Blue Ridge Surgery Center	ASC	-	6,127	6,127	100%
Raleigh Plastic Surgery	ASC	-	319	319	100%
Raleigh Orthopedic Surgery	ASC	-	5,513	5,513	100%
Rex Surgery Center Wakefield	ASC	-	2,131	2,131	100%
Rex Surgery Center Cary	ASC	-	4,584	4,584	100%
Rex Hospital	Hospital Shared	8,334	11,942	20,276	59%
Capital City Surgery Center	ASC	-	6,822	6,822	100%
WakeMed	Hospital Shared	7,988	11,276	19,264	59%
WakeMed Cary Hospital	Hospital Shared	3,142	3,740	6,882	54%
Holly Springs Surgery Center	ASC	-	2,217	2,217	100%
Triangle Orthopedic Surgery Center	ASC	-	2,682	2,682	100%
Duke Raleigh Hospital	Hospital Shared	3,568	7,415	10,983	68%
Totals		23,032	64,768	87,800	74%

Source: 2021 SMFP, Table 6B.

As the table above shows, 74% of the total Wake County surgical cases in FFY2019 were performed as ambulatory (outpatient) surgeries. Wake County currently has 16 existing and approved ASCs. Based on the fact that 74 percent of Wake County’s FFY2019 surgical cases were ambulatory surgery cases and that ASC operating rooms represent 34.5 percent of the total existing and approved Wake County operating rooms, projects proposing the development of ASC operating rooms would represent more effective alternatives.

Therefore, the applications submitted by **Valleygate Garner ASC, Orthopaedic Garner ASC, Duke Garner ASC** and **Duke Green Level ASC** are the more effective proposals with respect to this comparative factor. The **WakeMed Cary Hospital** and **UNC REX Hospital** applications are less effective with respect to this comparative factor.

**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 ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”*