

**Comments in Opposition to
Project ID # J-011753-19-18 – Duke University Health System**

Comments Submitted by Wake Spine and Specialty Surgery Center, LLC (“WSSSC”)

Pursuant to NCGS § 131E-185, WSSSC submits the following comments in opposition to the CON application submitted by Duke University Health System (“DUHS”).

“Inadvertent” Error Leads to Unnecessary Duplication of Service in Wake County

On page 22 of the CON application at the beginning of the Demonstration of Need discussion, DUHS states:

“DUHS currently operates 15 hospital based ORs in Wake County at DRAH, a facility that has experienced significant growth in surgery, especially outpatient surgery. While total surgical cases performed in the surgical suite at DRAH continue to steadily increase, DUHS notes that surgical cases reported as performed only in licensed ORs are lower in DRAH's 2019 Hospital License Renewal Application (HLRA) compared to the reported cases in previous HLRA's. When preparing HLRA's in previous years, DRAH inadvertently included all cases performed in the surgical suite, including surgical cases in both licensed ORs and in hospital-based procedure rooms. Overall surgical volume has steadily increased.”

DUHS makes this statement, then moves on. The problem with this “inadvertent” error is that it has already caused and will continue to cause the unnecessary duplication of OR services in Wake County. First, the error in data reporting in the 2017 HLRA led to an incorrect need determination of four operating rooms in Wake County in the 2018 SMFP and second, the error in data reporting in the 2018 HLRA has led to an incorrect need determination of two operating rooms in Wake County in the 2019 SMFP. As a result, six unnecessary ORs will eventually be approved to be developed in Wake County and DUHS want to benefit from its error in data reporting.

The following table illustrates how DUHS' error in data reporting resulted in an incorrect need determination in both the 2018 SMFP and 2019 SMFP.

	FY: July-June	
HLRA Reported Data	2017	2018
IP - OR Cases	4,389	4,094
OP - OR Cases	10,855	11,084
OP - PR Cases		6,713
SMFP Projected OR Need	2018	2019
IP - OR Cases	4,389	4,094
OP - OR Cases	10,855	11,084
DRAH OR Deficit	6.77	6.56
Wake OR Deficit	6.00	2.34
SMFP Wake OR Need	6.00	2.00
	FY: July-June	
2019 CON Application Reported Data	2017	2018
IP - OR Cases	3,754	3,529
OP - OR Cases	6,238	6,643
Corrected DRAH OR Deficit	1.47	1.43
Other Wake Facility OR Deficit	0.37	1.78
OR Placeholder	0.00	-6.00
Corrected Wake OR Deficit	1.84	-2.79
Corrected SMFP Wake OR Need	2.00	0.00
Duplicative ORs Due to DRAH Reporting Error	4.00	2.00

DUHS' 2018 CON application to develop the Green Level ASC was denied along with several other CON applications for operating room in Wake County, resulting in two applicants being approved for one operating room each for a total of two operating rooms. If DUHS had not "inadvertently" reported erroneous data in their 2017 HLRA, then no other operating rooms would have been available in the 2018 SMFP for Wake County, as there would have only been a need determination for two operating rooms. However, DUHS did "inadvertently" report erroneous data in their 2017 HLRA and as a result four more operating rooms were unnecessarily available in the 2018 SMFP. DUHS benefited from their reporting error by being approved through a settlement with the Agency for one operating room and the opportunity to develop a freestanding ASC in western Wake County.

DUHS' 2019 CON application to expand the Green Level ASC by two operating rooms should be denied. If DUHS had not "inadvertently" reported erroneous data in their 2018 HLRA, then no operating rooms would have been available in the 2019 SMFP for Wake County. However, DUHS did "inadvertently" report erroneous data in their 2018 HLRA and as a result two operating rooms were unnecessarily made available in the 2019 SMFP. DUHS should not benefit once again from their reporting error by having their CON application to expand the Green Level ASC by two operating room approved.

DUHS' "inadvertent" error in reporting its operating room procedures in the 2017 HLRA has resulted in over \$43.6 million in unnecessarily duplicated operating room construction in Wake County and now DUHS want to add an additional \$6.0 million to that total.

Demonstrate Need for Two Additional Operating Rooms

On pages 22 and 23 of the CON application, DUHS states:

"For the foregoing reasons, in determining the best way to meet patient needs for surgical services, a review of historical surgical utilization at DRAH should not be limited to surgical cases performed only in licensed ORs. Rather, when considering the need DUHS has for additional ambulatory surgical capacity in Wake County, consideration of DRAH's total ambulatory surgical utilization (including cases performed in ORs and hospital-based procedure rooms) is relevant and appropriate."

It's safe to say that DUHS has already benefited from "inadvertently" reporting erroneous data, which includes exactly what they recommend should be considered in the statement; the use of procedures performed in procedure rooms to support development of operating rooms. The standard methodology does not utilize any procedure room volume in determining operating room deficits and should not be considered in support of developing operating rooms.

In fact, DUHS reports the following OP cases performed in DRAH's four procedure rooms:

CON Application Page 122	FY2015	FY2016	FY2017	FY2018	FY2019
OP - PR Cases	3,173	3,657	3,817	3,880	4,125

In FY2018, it can be calculated that 970 procedures were performed in each of the four operating rooms. Green Level ASC will have five procedure rooms and DUHS proposes to only perform 164 procedure in each procedure room in FY2025.

On pages 22 and 23 of the CON application, DUHS states:

“Therefore, DRAH has accommodated a portion of its growing surgical volume in recent years in its procedure rooms. The majority of these surgical cases performed in a procedure room are appropriate for an ASC setting (based on acuity, anesthesia and other coverage needs, and procedure type; see Section Q for a discussion of the criteria used to determine ASC-appropriate cases). Therefore, it would be beneficial to patients and payors from a cost perspective to have such surgical procedures performed in an ASC rather than in a hospital setting.”

DUHS performs a multi-step methodology to project the number of OP cases that will shift from DRAH to Green Level ASC. In Step 10, DUHS assumes that the 88.6 percent of OP orthopaedic cases that shift to Green Level ASC will shift from DRAH operating rooms (876 procedures) and 11.4 percent of OP orthopaedic cases that shift to Green Level ASC will shift from DRAH procedure rooms (113 procedure). However, DUHS then assumes that 100.0 percent of the shifting OP cases from DRAH will then be performed in Green Level ASC operating rooms. If an OP cases can be performed in a procedure at DRAH, then there is no reason that it cannot be performed in a Green Level ASC procedure room.

Strangely enough, DUHS primary concern in the previous statement was that it has had to accommodate a portion of its growing surgical volume in its procedure rooms but even after shifting 2,876 procedures to Green Level ASC, DUHS still projects that the number of procedures performed in each of the four procedure rooms at DRAH will increase to 1,059 procedures from 970 procedures in FY2018. DUHS proposes to only perform 164 procedure in each procedure room in FY2025.

DUHS states that “the majority of these surgical cases performed in a procedure room are appropriate for an ASC setting” but does not project to shift any procedure room cases volume from DRAH to the procedure rooms at Green Level ASC. DUHS could propose to shift 75.0 percent of the DRAH

FY2025 procedure room volume to the Green Level ASC procedure rooms and those five procedure rooms will still be performing less than 1,000 procedures each or only 4 procedure per day. This would not require a CON application for unnecessary operating rooms and the shifting procedure room cases would still benefit from the following, as noted on pages 27 and 64 in the CON application:

- lower charge and cost structure compared to the current hospital-based charges and costs
- enhance geographic access to ambulatory services
- provide access to services for the communities DUHS serves
- align primary and specialty care services
- continue to ensure access and services to Wake County and increase lives touched across the local community
- maximize existing DUHS capacity
- where possible and strategically appropriate, consolidate smaller sites for efficiency and community visibility
- demonstrate to payers that DUHS is an essential network participant within current and emerging value-based care networks