COMMENTS IN OPPOSITION FROM OAKVIEW ASC, LLC

Regarding Competing Applications for Operating Rooms in Wake County:

J-012253-22 Triangle Vascular Care

J-012261-22 Duke Health Green Level Ambulatory Surgical Center

J-012264-22 WakeMed Garner Hospital

J-012260-22 Rex Hospital

J-012248-22 KM Surgery Center

Oakview ASC, LLC (Oakview), respectfully submits these comments for the Agency's consideration in its conduct of the 2022 Wake County Operating Room (OR) review.[1] In this review, six applicants filed certificate of need (CON) applications seeking CON approval to develop a total of nine new ORs in Wake County.

- Oakview proposes to develop a single-specialty ophthalmic ambulatory surgery center (ASC) with one OR and one procedure room (PR).
- Triangle Vascular Care (TVC) proposes to develop an ASC with one OR and two PRs for vascular access procedures.
- KM Surgery Center (KM) proposes to develop a multi-specialty ASC with one OR and two PRs with a focus on urology procedures.
- Duke Health Green Level Ambulatory Surgical Center (Duke Green Level ASC) proposes to "reclassify" two procedure rooms as ORs in its approved ASC.
- Rex Hospital (Rex) proposes to add two ORs to the current 27 ORs at its main hospital.
- WakeMed Garner Hospital (WakeMed Garner) proposes to develop two ORs as part of a new hospital.

In accordance with N.C. Gen. Stat. § 131E-185, Oakview offers comments on each application with specific attention to:

1. Facts relating to the service area proposed in the application;
2. Facts relating to the representations made by the applicant in its application, and its ability to perform or fulfill those representations; and
3. Discussion of whether the material in each application and other relevant factual material shows the application complies with relevant review criteria and performance standards.

The Agency must review each application independently against the criteria (without considering the competing applications) and determine whether each "is either consistent with or not in conflict with these criteria" (N.C. Gen. Stat. §§ 131E–183[a]). Based on the following, only the Oakview application demonstrated conformity with the applicable criteria:

[1] Nothing in these Comments is intended to amend the Oakview Application, and nothing contained here should be considered an amendment to the Oakview Application.

COMMENTS SPECIFIC TO TRIANGLE VASCULAR CARE

Triangle Vascular Care (TVC) is the name of the facility that two Triangle Vascular Associates (TVA) entities propose to develop in Cary.[2]

For many years, the TVA physician office practice has operated a Fresenius (now Azura) office-based vascular center providing patients with comprehensive vascular procedures in Cary (TVC app., p. 26). TVC seeks a new vascular access ASC to serve TVA patients in Cary.

TVC's ASC proposal should be denied as it is duplicative of Azura's Raleigh Access Center (the RAC), which was already CON approved to serve 75% of TVA's patients.

CRITERION (1)

(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.

Policy GEN-3: Basic Principles

"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."

Although the TVC proposal to develop an ASC with one OR and two PRs is consistent with the 2022 SMFP Need Determination, it is not consistent with Policy GEN-3 and therefore does not conform to Criterion (1). The TVC proposal is not consistent with Policy GEN-3 because:

[2] The TVC applicant entities are American Access Care of NC ASC, LLC (whose sole member is TVA), and AAC Management Services, LLC, a subsidiary of Azura Vascular Care (Azura or AVC), a Fresenius Vascular subsidiary (TVC app., p. 16).

- TVC's proposal will not promote access or value because it duplicates the RAC, which now operates with CON approval in an expanded facility in Wake County.
- The RAC was approved to serve 75% of patients shifting their care from TVA's office-based center in Cary to the RAC; the TVC population to be served is the very same population the Agency approved the RAC to serve.
- TVA will not enhance access because the RAC has ample capacity and is reasonably geographically accessible to all residents of Wake County and the other counties served by TVA physicians .
- TVC's project will reduce healthcare value by shifting vascular access procedures that TVA safely performs in its physician office to a higher-cost ASC adjacent to its Cary office. Less than 5% of the procedures TVC projects require an ASC or hospital outpatient setting.

In 2017, Azura and its physicians first petitioned Agency planners to identify a need to move office-based vascular care to the ASC setting.[3] Opponents stressed that such a petition was not driven by any demonstrated clinical need to perform those procedures in an ASC.[4] The Agency Report agreed, concluding the petition was financially motivated by declining Medicare office-based reimbursement:

> *The impetus for the petition is that the Centers for Medicare and Medicaid Services (CMS) instituted a bundled payments structure for vascular access procedures on January 1, 2017.*

The Agency denied the 2017 Petition.[5]

In 2018, Azura physician practices again petitioned, arguing Medicare payment reductions would make office-based centers "no longer financially feasible."[6] Multiple commenters responded, stating:

> *By the very nature of the proposal, the Petitioners are asking to move these procedures to a higher cost setting.*
>
> ***
>
> *Petitioner is requesting to increase costs through conversion of office-based procedure suites to licensed ambulatory surgery centers.*
>
> ***

[3] The 2017 petition is attached as Exhibit A.
[4] Comments on the 2017 petition are attached as Exhibit B
[5] The Agency's 2017 report is attached as Exhibit C.
[6] The 2018 petition is attached as Exhibit D.

> *The petitioner acknowledges that the described vascular procedures can be safely provided in a physician office or clinic setting.*
>
> *Approval of the petition would establish an exemption that facilitates the development of more costly settings in licensed and certified ambulatory surgery centers.*
>
> *Therefore, the petitioner's request for an exemption is not consistent with the Basic Principles of the State Medical Facilities Plan; Safety/Quality, Access, and Value.*[7]

The Agency recommended denial of the 2018 petition.[8]

Although the Agency was unwilling to create adjusted need determinations for vascular access ASCs, it did allow applicants to vie for identified OR need determinations. When OR needs appeared in the 2018 SMFP, the Agency approved an Azura vascular access center for both Mecklenburg and Wake Counties.

In Wake, the Agency initially approved the RAC as a one-OR/two-PR vascular access ASC and subsequently allowed the RAC to develop an additional PR when it was afforded an opportunity to lease an entire building floor to accommodate "projected growth."[9]

Most recently, in 2022, another petitioner sought a need for a vascular access ASC in Nash County. Notably, the Agency again recommended denial, suggesting that the State Health Coordinating Council consider instead creating one need determination for a vascular access ASC in each of the State's six multi-county Health Service Areas but with the specific provision that applications could not be filed for new vascular access ASCs in either Wake or Mecklenburg because each already has such an ASC (*See Exhibits L and M for the petition and the Agency's corresponding report).*

Historically, the Agency's planning staff has not been receptive to claims that lower reimbursement equates with a need for new vascular access ASCs in North Carolina. Instead, the Agency has allowed vascular access ASC applicants the opportunity to file CON applications to assert the need for specific ASC proposals. In its most recent report, the Agency's planners have recommended against a need that would allow for future vascular access ASC applications in either Wake or Mecklenburg Counties *because those counties already have such ASC access*.

TVC argues that office-based vascular access services are impractical because Medicare pays less for services in this setting. TVC cites a 39% reduction in payments since 2017, which they explain as due to a reduction in Medicare payments for this service in an office-based setting. In the CY 2018 Federal Register, however, CMS responded to commentors' concerns with an increase in

[7] Comments against the 2018 petition are included in Exhibit E.
[8] The Agency's 2018 report is attached as Exhibit F.
[9] The RAC was approved and expanded per Project ID#s J-11551-18 and J-11804-19.

payment. CMS stated, "We appreciate commenters' responses to our request for new information. After further reflection, we are persuaded by commenters' explanations regarding the complexities of care related to this patient population specifically and after reviewing these additional remarks, agree that these services are currently misvalued. Therefore, for CY 2018, we are finalizing the CY 2017 RUC-recommended work RVUs [i.e., relative value units] for CPT codes 36901–36909, consistent with the requests of public commenters."[10]

The table below illustrates the increase in Medicare's work RVUs from CY 2017 to CY 2018 for codes 36901–36909.

Code	CY 2017 Work RVU	CY 2018 Work RVU
36901	2.82	3.36
36902	4.24	4.83
36903	5.85	6.39
36904	6.73	7.50
36905	8.46	9.00
36906	9.88	10.42
36907	2.48	3.00
36908	3.73	4.25
36909	3.48	4.12

Source: Federal Register 82, No. 219, Wednesday, November 15, 2017, Rules and Regulations, 53091–53093.

Since CY 2018, CMS has not made further proposals on the payments for these codes. The Federal Register for the final CY 2019 payment rules addressed providers who requested that CMS provide additional reimbursement stability for vascular access services by increasing the work RVUs and direct PE inputs for CPT codes 36901–36909.[11] [12] TVC failed to address the increase in payment for these codes that occurred in 2018 and did not provide current evidence that these procedures are financially infeasible in an office setting.

Based on the application as filed, TVC has not demonstrated conformity with Policy GEN-3 and Criterion (1) in that TVC's application:

- Double-counts by projecting to serve the same patient population which the Agency already approved the RAC to serve;
- Ignores significant unused capacity at the RAC;

[10] Federal Register 82, No. 219, Wednesday, November 15, 2017, Rules and Regulations, 53017.
[11] Federal Register 82, No. 219, Friday, November 23, 2018, Rules and Regulations, 59473.
[12] "These comments [seeking further increases] are considered out of scope for the CY 2019 PFS final rule, as we did not make any proposals on these issues in the CY 2019 PFS Proposed Rule." *Ibid*.

- Fails to improve geographic access;
- Relies on a comparison to hospital costs that does not support its proposal; and
- Projects to provide only limited services that cannot already be offered safely and more cost-effectively in-office.

TVA Double-Counts by Projecting to Serve the Same TVA Patients as the RAC

The TVC application double-counts TVA patients on which the RAC approval was based. The RAC was approved in 2019 based on a demonstration of need centered on serving fully 75% of the vascular access cases served at the TVA Cary practice location, described as a "75% capture of Cary cases."

The RAC was approved in 2020 to expand, again relying on a proposed "shift" to the RAC of 75% of the vascular access cases served in its Cary practice location:

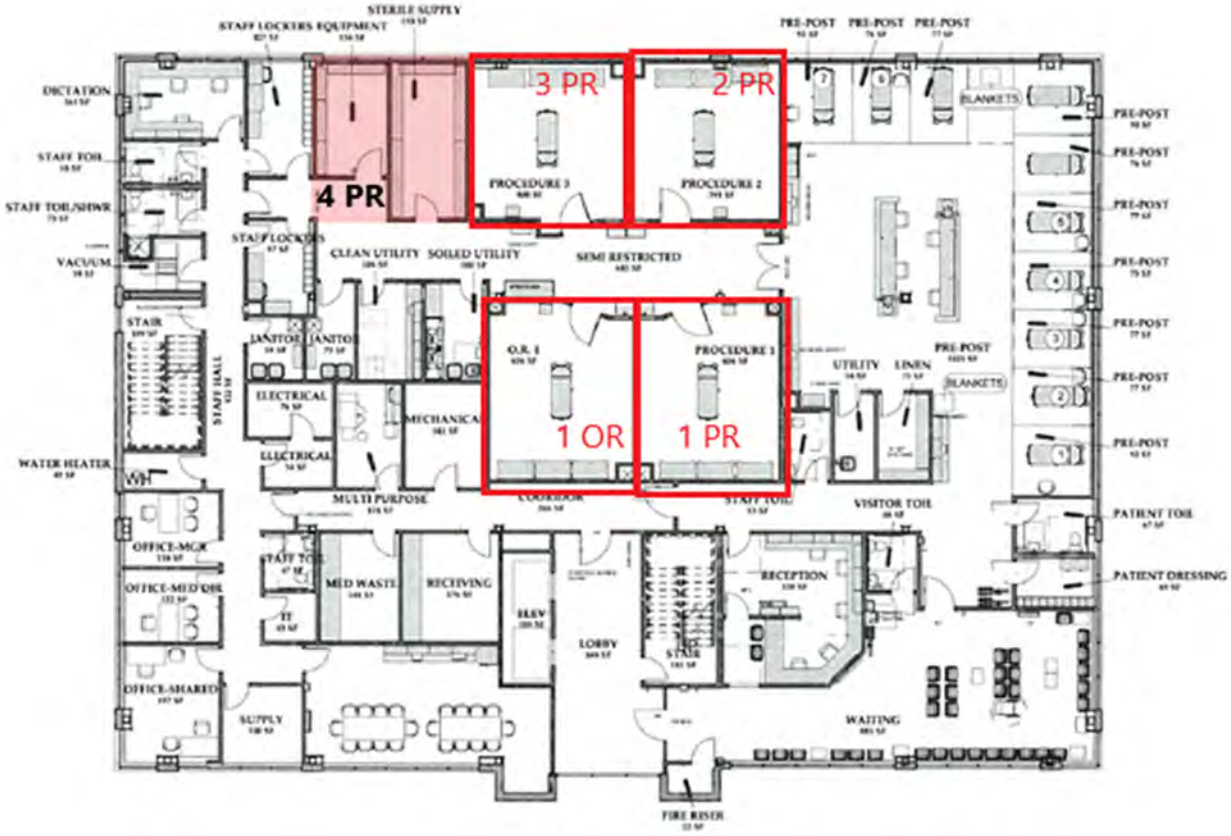
> *In RAC ASC's original application, the 2018 volume was estimated based on … procedures performed at the affiliated Cary and Raleigh vascular access centers that together will serve as the primary referral sources for the new proposed ASC in Raleigh.*
>
> ***
>
> *The projected utilization methodology has remained the same … **75% of case volumes from Cary will shift**.*

The Cary location noted above is the same location (2501 Weston Parkway) from which the TVC application now proposes to shift patients to the proposed TVC ASC in Cary. Specifically, the TVC application projections call for a 75%, 80%, and 85% shift of patients from the TVA office to the proposed TVC ASC in Cary (TVC App., p. 134). These very same patients were already projected to shift to the RAC, per the initial approval and subsequent expansion approval of the RAC. Seventy-five percent of the same patient population cannot shift to the RAC *and* shift to the proposed TVC ASC in Cary. To be clear, the references in the TVC application to a shift of patients "from the office-based TVA" are references to shifts from the same place (2510 Weston Parkway) described in the RAC application as shifts from "the VAC located in Cary," sometimes called shifts from the "Cary practice."

The RAC Has More Than Adequate Capacity for TVA Patients

The RAC was originally approved for one OR and two PRs in 6,800 square feet on the first floor of a building. The cost-overrun/expansion application approved in 2020 allows the RAC to develop one OR and three PRs in roughly 11,000 square feet occupying the *entire* second floor of its building. The RAC stated, "The increased square footage of the second floor will allow for the inclusion of a third procedure room **to accommodate current and future growth in demand**."

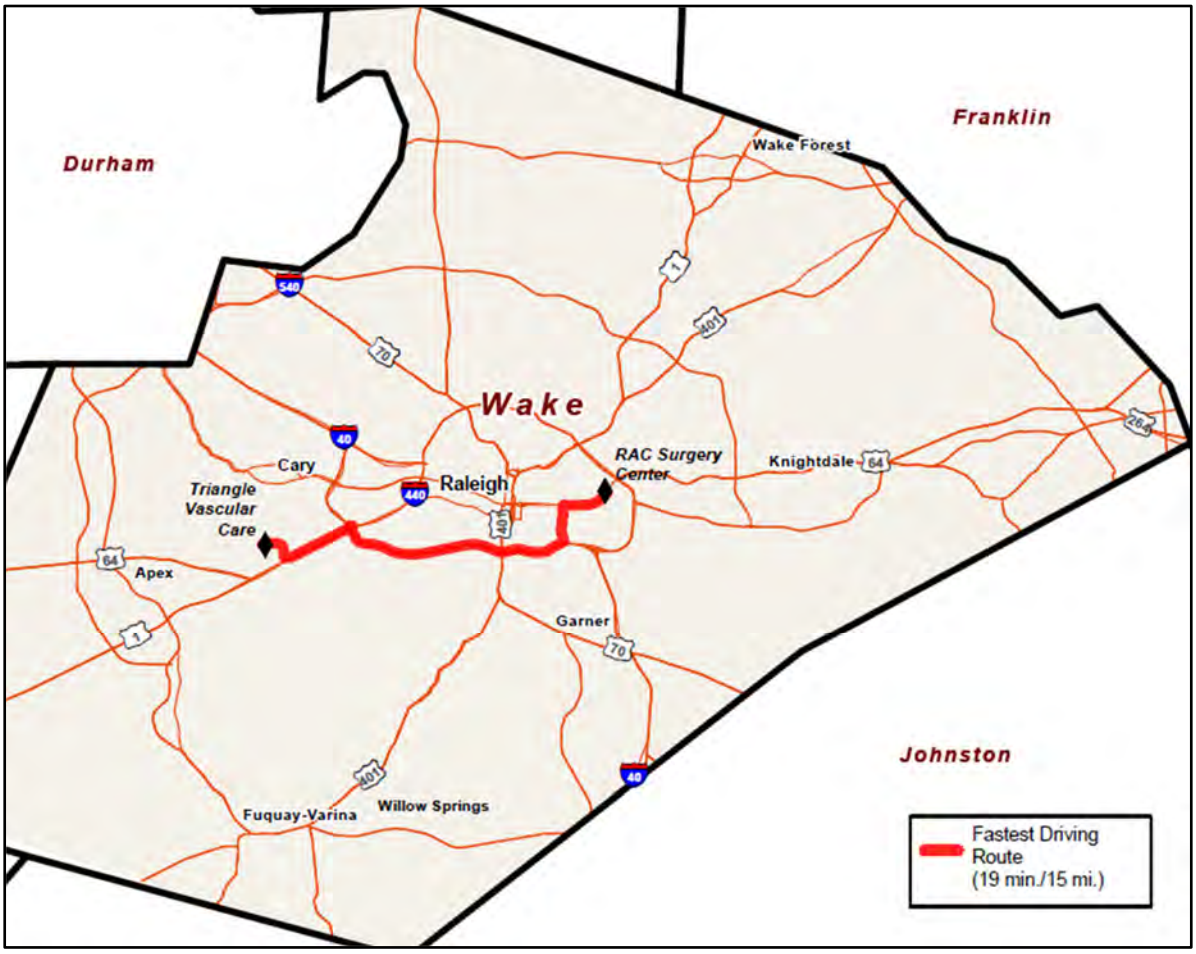
The RAC has space for further expansion. The floor plan for the expanded RAC shows one OR and three PRs plus space for a fourth procedure room. Adjacent to the third PR are two spaces labeled “Equipment” and “Sterile Supply,” which, taken together, have the same square footage as RAC’s third PR, as shown in the red shaded area below.



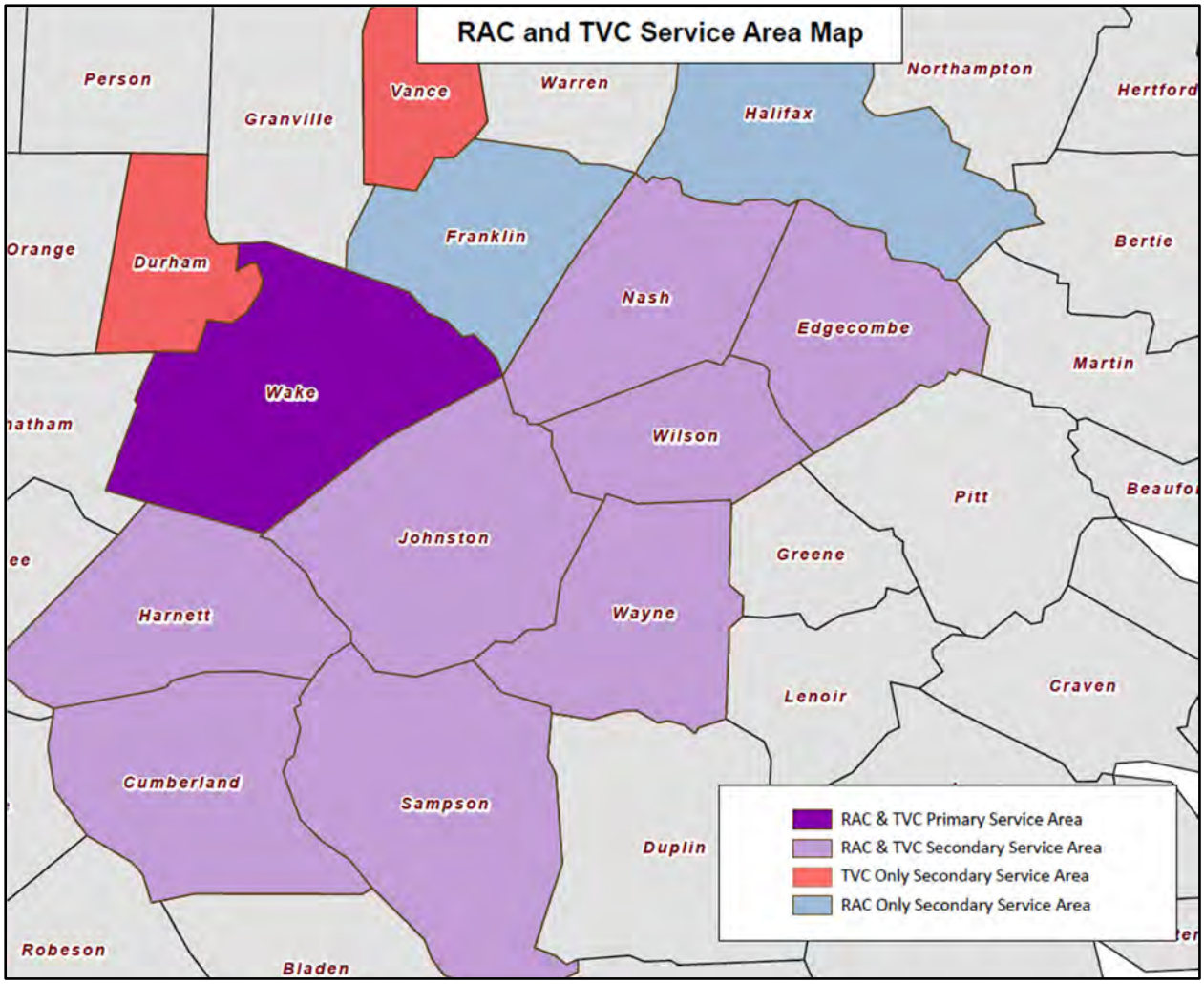
The RAC Offers Reasonable Geographic Access for TVA Patients

In the 2018 and 2019 RAC applications, Azura represented that the RAC location in Raleigh was geographically accessible for TVA patients and for all patients in Wake County and its multi-county service area. The distance between the RAC in Raleigh and the proposed TVC facility is relatively short, in terms of both mileage and travel time. According to Google Maps, the two locations are only about 15 miles and 19 minutes apart.

Driving Distance Between the RAC and TVC Facilities



The map below shows the overlap in the secondary service areas for TVC and the RAC. Most of the counties in TVC's secondary service area are closer to the RAC than to the TVC location.



Based on the information in the TVC application, a proposed shift of services from an office-based site to an ASC setting 15 miles away may be advantageous from a financial perspective for Azura, but the proposed shift will not enhance patient access or maximize healthcare value for resources expended. Wake County already has the RAC. The RAC is run by the same operator, offers the same services, and was approved based on the representation it would serve 75% of the patients from TVA's Cary practice location.

TVC has not shown the population's need for a vascular access center in Cary in addition to the location in Southeast Raleigh where the RAC now operates. Black or African Americans are more than three times as likely to have kidney failure compared to white Americans. Minority

populations have much higher rates of high blood pressure, diabetes, obesity, and heart disease, all of which increase risk for kidney disease. (See https://www.kidney.org/atoz/content/minorities-KD.) The RAC is in zip code 27610, which is home to primarily Black or African American residents (65.5%). (See https://www.unitedstateszipcodes.org/27610.) In contrast, the site proposed for the TVC ASC in Cary has a relatively small Black or African American population relative to the total area population. The people living in Cary in zip code 27511 are primarily white (75.7%). (See https://www.unitedstateszipcodes.org/27511.)

TVC Comparisons to Hospital Costs Do Not Support Its Approval

TVC notes benefits of an ASC as compared to a hospital outpatient department (HOPD). While these may be valid observations, they simply do not support the approval of TVC.[13] The Agency's approval of the RAC addressed the option of receiving vascular access care in an ASC for patients for whom it is medically necessary. The TVC application is not about avoiding costly hospital care; it is about shifting patients from a physician office with no facility fee to an ASC with both a physician and a facility fee. The increased cost comes without showing the quality of care being provided in the physician office is lacking. Any procedures by TVA physicians requiring an ASC have presumably already been shifted to the RAC; care that must be performed in a hospital will continue to be performed there.

TVA attempts to muddy the water by illustrating the cost saving of shifting services from a hospital to an ASC. On page 50 of its application, in the "Potential Cost Savings of Shifting Vascular Access Creation from Hospital to ASF," TVC footnotes an "AVC internal analysis, with 2019 national Medicare data." We have also analyzed the Medicare data. We are unable to verify that the TVA physicians perform the referenced CPT services. We did identify CPT codes for the services TVA does provide and found no instance where a facility-based fee is less than an office-based fee.

TVC Office-Based Center Already Provides a Comprehensive Range of Vascular Procedures

Nearly all the procedures TVA projects to provide at its ASC are already done in its office-based center. TVA physicians provide the mix of cases shown for 2019–2022, all within its office-based center. TVA projects to serve the listed cases for 2024–2026 in its proposed ASC. As one can readily see, the cases are almost entirely the same. Only fistula creation procedures are currently done outside the physician office. In 2026, these procedures account for only 122 of 2,977 procedures, or just 4.1%. Stated another way, 95.9% of the cases TVA proposes for its ASC are already safely performed at its in-office center in Cary, at a cost lower than those cases could be provided in the proposed ASC. Of the fistula creation procedures, about 20% can be safely performed in a physician office. Moving cases already safely performed by TVA physicians in-

[13] In its Required State Agency Findings, Project ID #: D-12193-22, July 15, 2022, p. 6, the Agency observed there was "no information … that explains why the data provided is relevant to the application and how the data supports projected utilization." The same observation holds true here.

office in Cary to be performed by the very same TVA physicians in a proposed ASC, also in Cary, will only increase the costs to patients and will not improve quality, access, or value.

TVA Procedures, Historical In-Office and Projected at TVC ASC

	Historical In-Office				ASC Projected		
	2019	**2020**	**2021**	**2022**	**2024**	**2025**	**2026**
Arteriogram - Treatment	121	154	141	151	117	126	136
Embolization (non-UEF)	38	26	65	26	20	22	24
ESRD Angioplasty	1,545	1,103	1,026	1,001	850	914	978
ESRD Catheter Change	73	88	110	108	83	90	97
ESRD Catheter Insertion	47	47	41	31	24	26	28
ESRD Catheter Other	6	3	6	2	2	2	2
ESRD Catheter Removal	52	41	50	46	35	38	41
ESRD Fistulogram	359	323	348	386	310	334	359
ESRD Other	9	4	4	22	17	18	19
Fistula Creation					120	120	122
ESRD Stents	353	624	605	600	483	521	560
ESRD Thrombectomy	100	45	51	43	42	45	48
Other Procedures	93	72	21	26	20	22	24
Pain Management Other	2	-	.	2	2	2	2
Pain Management Vertebroplasty	1	-	3	-	-	-	-
PICC	2	1	6	-	-	-	-
Ports	8	2	16	14	11	12	13
UFE	194	175	184	214	165	178	192
Vein Treatment Laser RF Faste	134	168	139	82	63	68	73
Vein Treatment Other	318	191	223	288	222	240	259
Total	3,455	3,067	3,039	3,042	2,586	2,778	2,977

** Totals may not foot due to Rounding*

Shifting services from office-based care to an ASC setting is for the physicians' benefit and, for most cases, is not based on patient need.

The takeaways regarding TVC's nonconformance with Criterion (1) are:

1. Azura represented that the RAC would serve 75% of the vascular access cases being performed by TVA physicians, and the Agency approved the RAC applications based on those representations. The TVC application double-counts patients expected to be served at the RAC.

2. The RAC has adequate capacity to serve all patients of both Azura physician groups in Wake County. In 2020, the Agency approved the RAC to add a third PR and increase

its square footage by over 61%. The RAC includes an equipment/supply area identical in size to the space needed for a fourth PR.

3. TVA patients have reasonable geographical access to the RAC. TVC and the RAC are only 15 miles and 19 minutes apart. Most of the counties in TVC's secondary service area are closer to the RAC than to TVC.
4. Of the procedures TVC projects in its third year of operation, 95.9% can be safely performed in a physician office at lower cost (physician plus facility fees) than in an ASC. Approval of TVC will increase healthcare costs, with no quality or access benefits.

For these reasons and others the Agency may discern, the TVC application is nonconforming with Criterion (1) and should not be approved.

CRITERION (3)

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

Reasonable and adequately supported utilization projections must show need for a proposed project. If projected utilization is not reasonable and adequately supported, the application cannot be approved.

The comments regarding TVC's nonconformance with Criterion (1) demonstrate that TVC has not adequately demonstrated that the population it intends to serve has an unmet need for the project. Those criticisms are incorporated here by reference.

TVA Double-Counts by Projecting to Serve the Same TVA Patients as the RAC

TVC's projected utilization is not reasonable or supported because it is premised on serving patients that its sister facility, the RAC, previously projected to serve. The RAC was CON approved based on a projection that 75% of TVA's office procedures would shift to the RAC.[14] As such, TVC cannot reasonably base its utilization projections on an intention to serve the same population identified to shift to the RAC. Historical utilization at the RAC since its opening in

[14] CON Application for Project ID #J-11551-18, p. 32.

June 2021 has underperformed the estimates provided in its approved CON application, and there remains adequate capacity for growth at the RAC. With that, TVC has not demonstrated that the population it identified has a need for services at a TVC ASC.

TVC Office-Based Center Already Provides a Comprehensive Range of Vascular Procedures

Nearly all the procedures TVA projects to provide at its ASC are already done in its office-based center. TVA physicians provide the mix of cases shown for 2019–2022, all within its office-based center. TVA projects to serve the listed cases for 2024–2026 in its proposed ASC. The cases are almost entirely the same. Only fistula creation procedures are currently done outside the physician office. In 2026, these procedures account for only 122 of 2,977 procedures, or just 4.1%. Stated another way, 95.9% of the cases TVA proposes for its ASC are already safely performed at its in-office center in Cary, at a cost lower than those cases could be provided in the proposed ASC. The population proposed to be served has no need for the TVC ASC, as the data show, the vast majority of procedures to be performed have historically been safely performed in an office-based center and can continue to be performed there. TVA has failed to show that the population it identified has a need for the facility it has proposed to develop.

The Small Number of Procedures Required to be Performed in an OR (Fistula Creations) Are Not Sufficient to Justify the Need for This Project

TVC does not provide a reasonable basis for the number of OR procedures it projects. TVC states, "Historically, fistula creations have not been performed in office-based vascular access centers," and notes that some fistula creation patients require additional procedures. On page 136 of its application, TVC projects it will perform 122 fistula creation and related procedures in the OR in its third year. The other procedures can and have been performed in physicians' offices.

Substituting the projected OR cases with the only service not currently being provided in the office-based setting (the fistula creation procedures) reduces the need to 0.11 ORs in year three. This does not meet the performance standard, and TVC does not demonstrate a need for the requested OR.

TVC OR Need Calculation, Limited to Fistula Creation Procedures

Surgical Cases	**2024**	**2025**	**2026**
# of C-Sections Performed in Dedicated C-Section ORs			
# of Inpatient Surgical Cases [(2)]			
# of Outpatient Surgical Cases	**120**	**120**	**122**
Total # of Surgical Cases [(2)]	120	120	122
Case Times (from Section C, Question 12(c) or 12(d))			
Inpatient			
Outpatient	70.1	70.1	70.1
Surgical Hours			
Inpatient [(3)]			
Outpatient [(4)]	140.2	140.2	142.5
Total Surgical Hours	140.2	140.2	142.5
# of ORs Needed			
Group Assignment [(5)]	6	6	6
Standard Hours per OR per Year [(6)]	1312	1312	1312
Total Surgical Hours / Standard Hours per OR per Year	**0.11**	**0.11**	**0.11**

RAC Has Existing, Unused Capacity That Offsets the Need for This Project

The RAC 2022 License Renewal Application (LRA) and the TVC application include data showing the RAC performed significantly fewer cases than projected. The table below compares the estimated OR and PR cases for the first three years of operation to actual data from June 2021 through May 2022. For both types of cases, the actual volume was about half the estimated figure in the CON application.

RAC Surgery Center Volume

	Interim Year	Year 1	Year 2	Year 3
Projected OR Cases		1,558	1,814	1,875
Actual OR Cases^	420	732	n/a	n/a
Projected PR Cases		4,835	5,249	5,433
Actual Procedures^	1,693	2,744	n/a	n/a

Source: CON Application Project ID #J-11804-19, p. 64; CON Application Project ID #J-12253-22, p.140.
^ Year 1 actual volume for RAC is annualized based on year-to-date utilization from January through May 2022.

This lower volume at the RAC has resulted in fewer operating hours. In its original application, the RAC was projected to operate nine hours a day, five days a week.[15] In its 2022 LRA, the RAC reported operating two days a week for sixteen hours.[16] The RAC could improve access to surgical services and expand capacity simply by extending its hours to be in line with what was proposed in its original CON application. The RAC's unused capacity is sufficient to meet demand for all TVC's projected OR cases. TVC has not demonstrated a need for the OR in its proposed project.

Azura projected the future OR utilization for the RAC in its application. Combining the volume for RAC with the volume of TVC procedures that cannot be performed in an office (fistula creations) in Year 3 results in a need for less than one OR. The existing capacity at the RAC is sufficient to meet the future needs of Azura's Raleigh and Cary physician practices, despite the double-counting of surgery cases for TVA's physicians at both facilities. Shifting services from office-based care to an ASC setting is for the physicians' benefit and, for most cases, is not based on patient need.

Azura Vascular Care Project OR Need

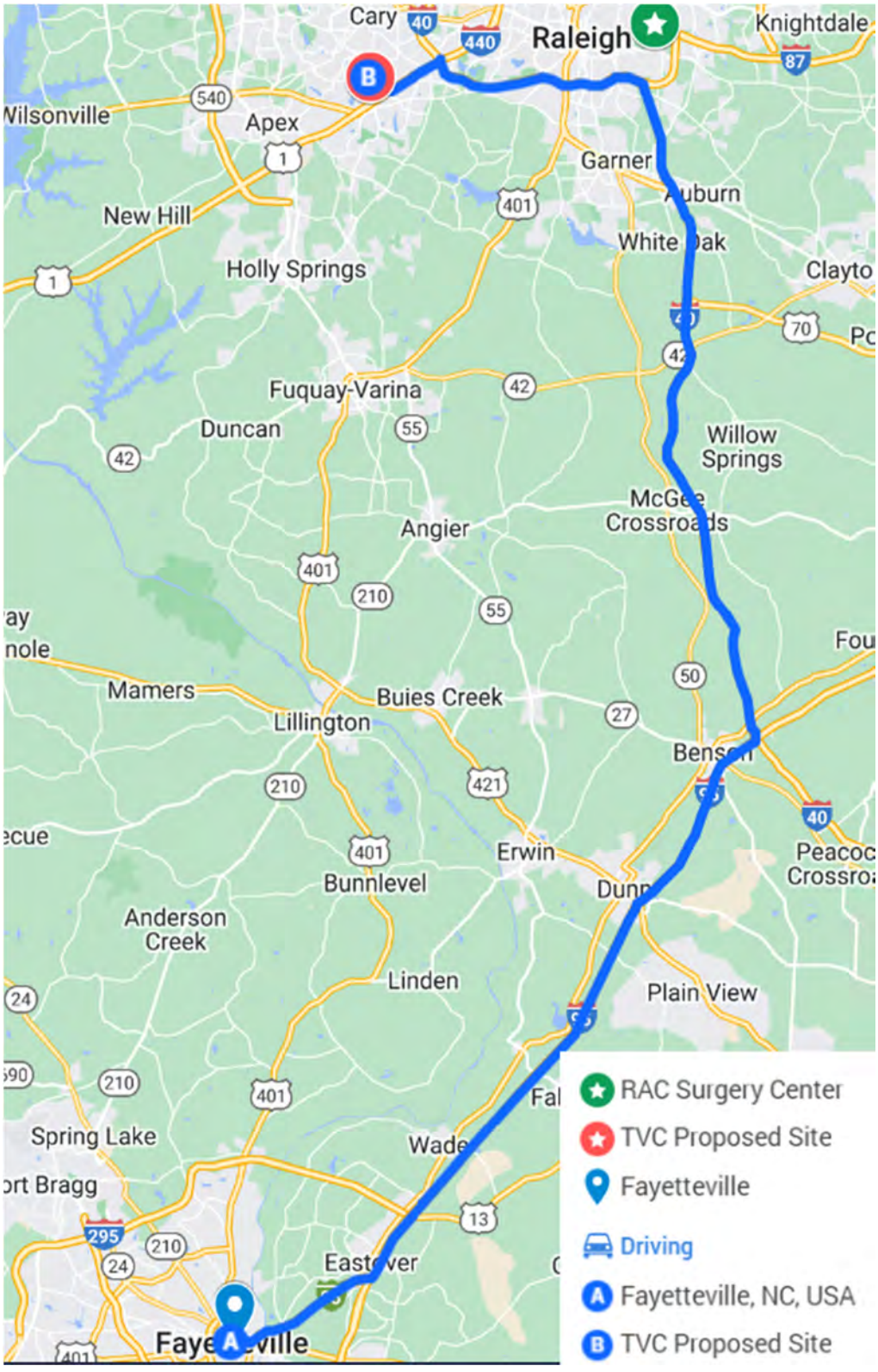
Facility	**2024**	**2025**	**2026**
TVC	0.11	0.11	0.11
RAC	0.80	0.83	0.87
Total ORs Needed	0.91	0.94	0.98
Licensed ORs	1.0	1.0	1.0
Deficit (Surplus)	(0.09)	(0.06)	(0.02)

Source: CON Application # J-12553-22, p. 141.

TVC projects significant patient volumes from Cumberland County. However, as shown on the map below, patients travelling from Fayetteville in Cumberland County would likely travel via I-95 and I-40 such that they would essentially drive through Southeast Raleigh and pass the area in which RAC is located before reaching the proposed TVC facility. The routing depicted on the map strongly suggests that patients from Cumberland County could reach the RAC as or more easily than the TVC site in Cary. For these patients, TVC would do little, if anything, to better their geographic access. As discussed, RAC reports operating only two days per week, suggesting it has ample opportunity expand its hours of operation. Moreover, RAC has physical capacity to accommodate patient demand and serve patients who can already access RAC via major roadways from counties such as Cumberland.

[15] CON application # J-11551-18, p. 16.
[16] 2022 LRA, p. 4.

Route from Fayetteville to Proposed TVC Location



Source: Google Maps

CRITERION (4)

(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 has not adequately demonstrated that the alternative proposed in its application is the most effective alternative to meet the need because:

- TVC does not demonstrate the need for its proposed project, or that the projected utilization is reasonable and adequately supported. See the discussions about need and projected utilization under Criterion (3) above. A project that does not provide reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- TVC does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. See the discussion on financial feasibility under Criterion (5) below. TVC does not demonstrate that developing the project is financially feasible, and thus cannot demonstrate that the proposed alternative is the most effective alternative to meet the need.
- TVC does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. See the discussion about unnecessary duplication under Criterion (6) below. An unnecessarily duplicative project cannot be the most effective alternative to meet the need.
- TVC does not provide credible information to explain why it believes its proposed project is the most effective alternative.
- Based on the information in the TVC application as filed, the least costly and most effective alternative for TVA patients is for TVA physicians to continue performing procedures that can be safely performed in a physician office in the TVA office-based center and to perform other procedures at the RAC. TVC presented no credible evidence why this is not the superior alternative based on access, quality, and cost.
- TVC is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

For these reasons and such others as the Agency may discern, the TVC application is not conforming with Criterion (4).

CRITERION (5)

(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.

TVC's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). As projected revenues and expenses are based in part on projected utilization, TVC's projected revenues and expenses are also questionable, rendering the TVC application non-conforming to Criterion (5). See Criterion (3) discussion above.

CRITERION (6)

(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's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). Those comments are incorporated here by reference. Because the TVC utilization is questionable, the applicant does not adequately demonstrate that its facility as proposed is needed. Therefore, TVC does not demonstrate its conformity with Criterion (6).

TVC does not adequately demonstrate that its proposal would not result in an unnecessary duplication of existing or approved services in the service area because TVC does not adequately demonstrate that its proposed OR is needed in the service area. See the discussion regarding need and projected utilization found in Criterion (3) which is incorporated herein by reference.

TVC's proposed project is a duplication of existing health services capabilities. The vast majority of procedures TVC proposes to include in the ASC are already provided in a physician office setting. TVA physicians in Cary can refer patients and perform procedures at the RAC, which opened in June 2021. The RAC CON applications assumed volume from TVA to justify its volume projections. The RAC assumed 75% of "ASC-appropriate" office-based procedures would shift from the TVA office-based center to the RAC.[17] Per Google Maps, the RAC is within 15 miles or 19 minutes' drive time from the proposed TVC facility and is reasonably geographically accessible for TVA patients. Approving the proposed project would unnecessarily duplicate existing capacity for vascular access procedures in Wake County.

[17] CON Application for Project ID # J-11551-18, Form C, p. 80.

The RAC opened in June 2021. In its change of scope CON application (Project ID# J-11804-19), the RAC projected to perform over 1,500 OR cases and 4,800 PR cases in its first full year of operation. Part of the reasoning for the change of scope in the application was that volume was assumed to grow more quickly than anticipated, requiring an additional PR to ensure capacity for growth. The RAC now has one licensed OR and three PRs for vascular access procedures.[18] Its floor plan shows space for a fourth PR if needed,[19] as discussed in detail under the critique of the RAC's conformance with Policy GEN-3. No additional ORs are needed to increase capacity.

The RAC 2022 LRA and the TVC application include data for the RAC showing it performed significantly fewer cases than projected. The table below compares the estimated OR and PR cases for the first three years of operation, compared to actual data from June 2021 through May 2022. For both types of cases, the actual volume was about half the estimated figure in the CON application.

RAC Surgery Center Volume

	Interim Year	Year 1	Year 2	Year 3
Projected OR Cases		1,558	1,814	1,875
Actual OR Cases^	420	732	n/a	n/a
Projected PR Cases		4,835	5,249	5,433
Actual Procedures^	1,693	2,744	n/a	n/a

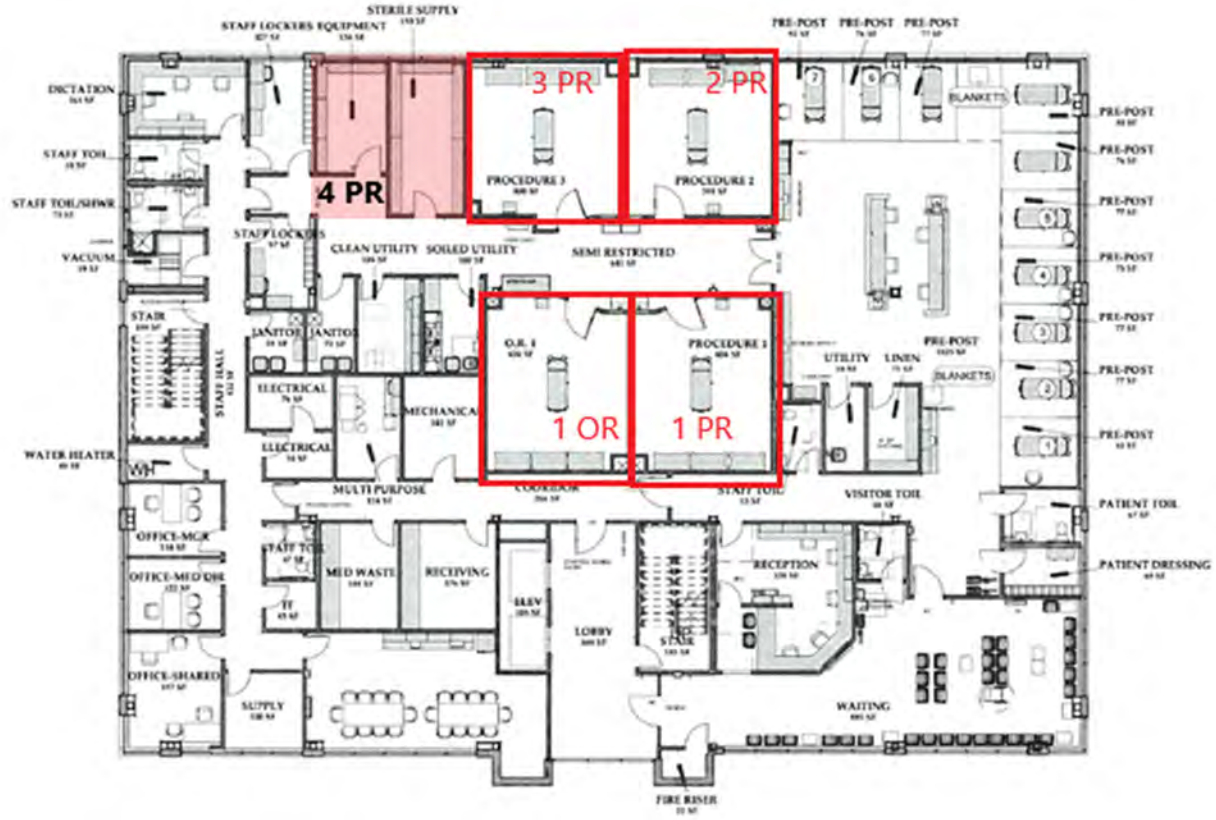
Source: CON Application Project ID #J-11804-19, p. 64; CON Application Project ID #J-12253-22, p.140.
^ Year 1 actual volume for RAC is annualized based on year-to-date utilization from January through May 2022.

This lower volume at the RAC has resulted in fewer operating hours. In its original application, the RAC was projected to operate nine hours a day, five days a week.[20] In its 2022 LRA, the RAC reported operating two days a week for sixteen hours.[21] The RAC's current capacity is sufficient to meet demand for all TVA patients. Should there be a future increase in demand, it could be met by increasing operating hours to be in line with what the RAC proposed in its original CON application.

The RAC's change of scope in its application indicated that occupying the entire second floor of its building and relocating all services to this suite would enable it to "meet the growing needs of the patient population with the third procedure room, and avoid additional expenditure necessary to renovate shell space in the future."[22] The floorplan below, from the 2019 application, shows the

[18] 2022 License Renewal Application, p. 7.
[19] CON # J-11804-19, Exhibit K-5.2.
[20] CON application # J-11551-18, p. 16.
[21] 2022 LRA, p. 4.
[22] CON application # J-11804-19, p. 34.

RAC has room in its building footprint to renovate and add a fourth PR to accommodate any volume increases.[23] It also has the option of staffing the facility on additional weekdays to add capacity for vascular access cases.



The RAC's CON application overstated volume for the RAC and TVC. The volume projections for the proposed TVC facility include updated volume estimates for the RAC that are much lower than its previous projections. The base volumes from which the RAC projected future volumes include patients from the TVA office in Cary.[24] These same patients are also included in the volumes for the proposed TVC facility. TVC assumed a shift of 75% of office-based procedures from TVA in Year 1, increasing in future years.[25] There is no discussion about what will happen to the RAC's volume when the TVC ASC opens in 2024, or what percentage of these patients will shift back to the Cary location. The applicant thus erroneously double-counts TVA cases.

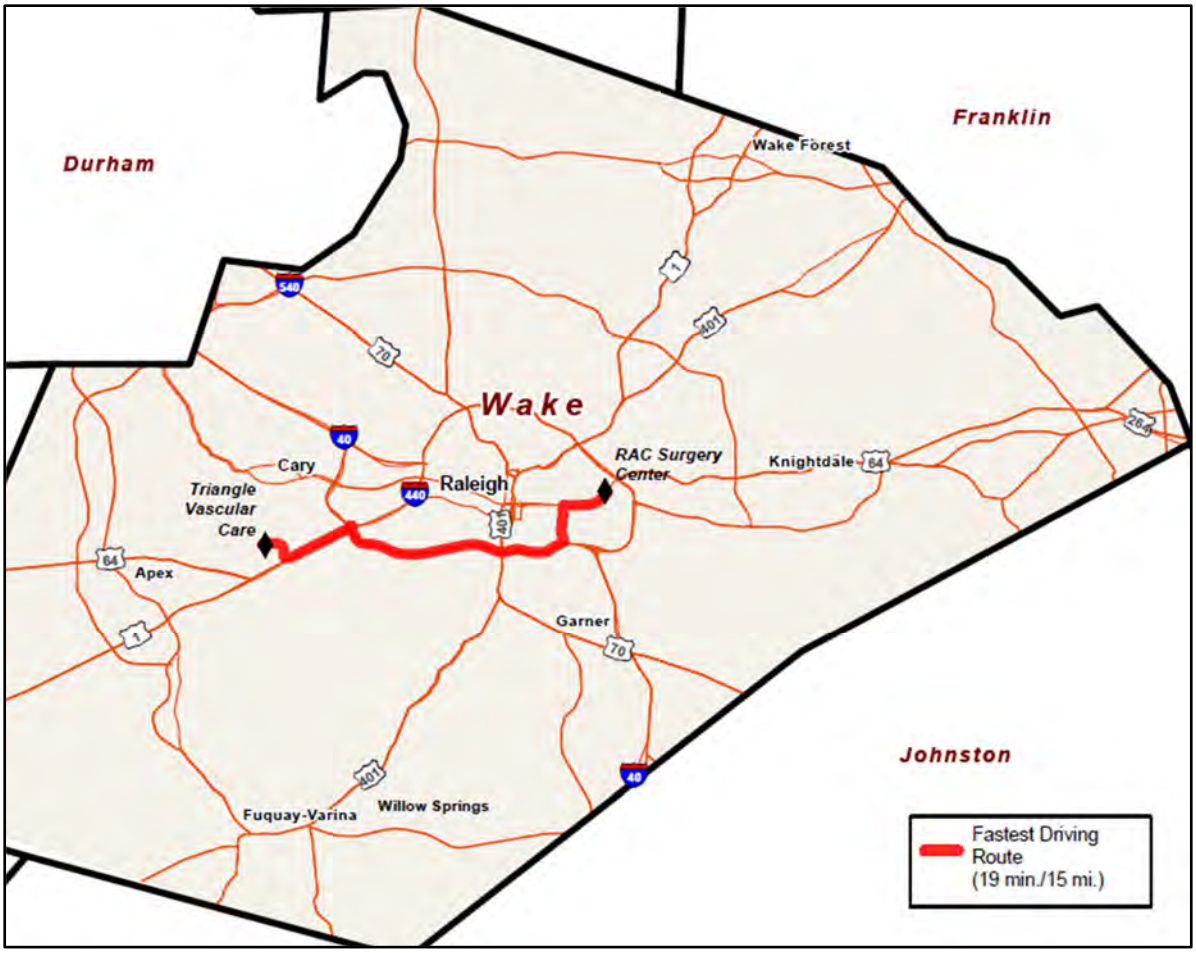
The unnecessary creation of a second vascular access ASC adjacent to the TVA offices would also increase community healthcare costs, as the TVA physicians would now find it convenient to move procedures safely performed in their physician office to an ASC where Azura can also charge a

[23] CON # J-11804-19, Exhibit K-5.2.
[24] CON application Project ID # J-12253-22, p. 140.
[25] CON application Project ID # J-12253-22, p. 134.

facility fee. We suspect such procedures moved from the North Carolina Nephrology Associates office to the RAC when it opened. Moving procedures safely done in a physician office back from the RAC to the physician office can further increase the capacity of the RAC for procedures that require an ASC.

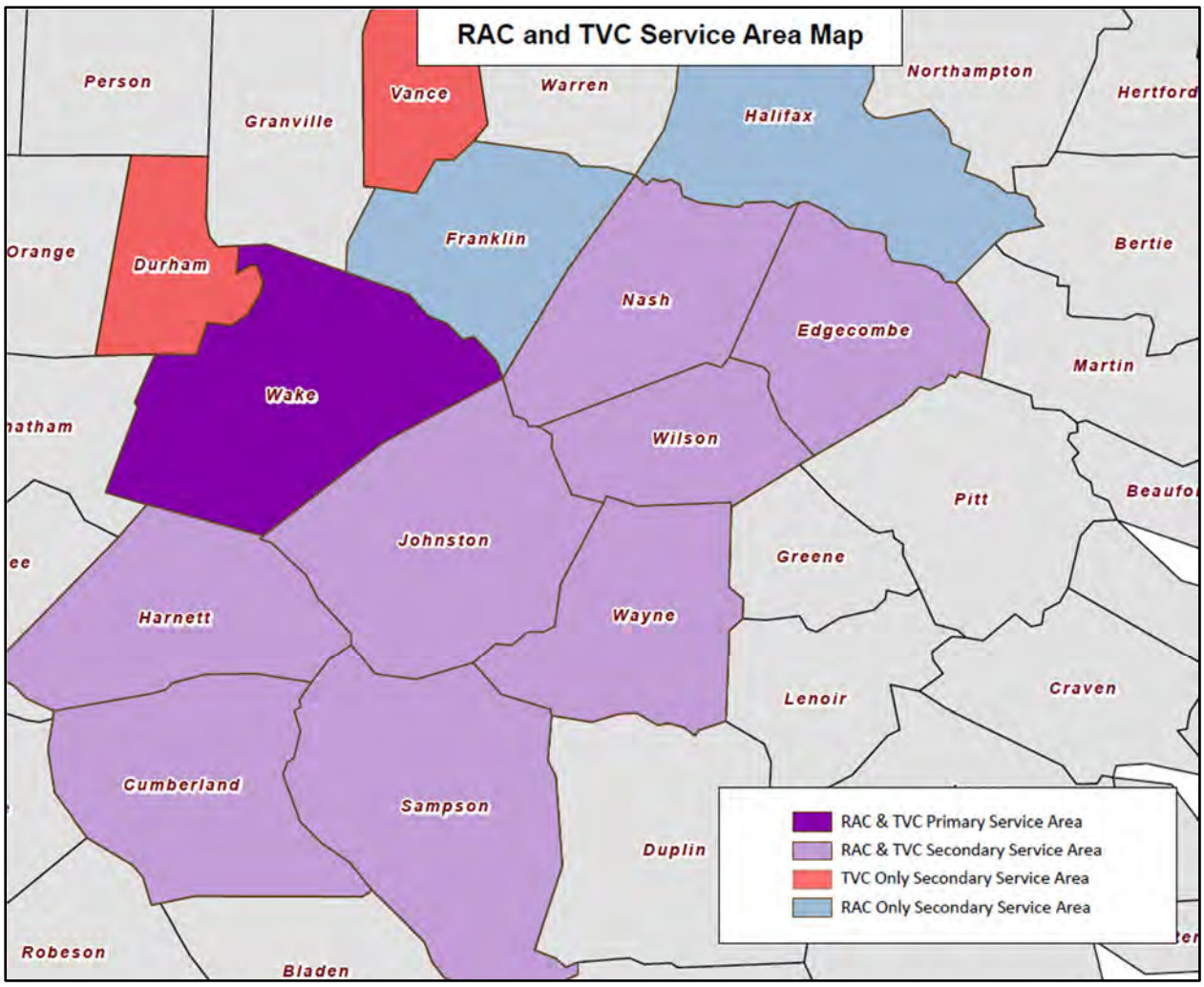
The TVC ASC is not needed to provide reasonable geographic access for Wake County residents. The distance between the RAC in Raleigh and the proposed TVC ASC is relatively short, in terms of both mileage and travel time. According to Google Maps, the two locations are only about 15 miles and 19 minutes apart. Azura did not say this was a barrier to access in its RAC applications. The original RAC CON application for Project ID # J-11551-18 assumed 75% of cases performed in the TVA Cary office would shift to the RAC surgery center upon opening. Azura clearly did not believe this would present any access challenges to patients from the Cary location. The RAC can continue to serve patients from the TVA practice without the cost of constructing a new facility. The map below shows the distance and travel time route from the RAC to the proposed TVC ASC in Cary.

Driving Distance Between RAC and TVC Facilities



Source: Esri.

The service area for both the RAC and the proposed TVC ASC include multiple counties outside of Wake County. TVC's patient origin assumed only 24% of its patients will originate in Wake County, with counties such as Cumberland (23%) and Wilson (10%) accounting for large shares of case volumes. This indicates that local geographic access in Cary is not a critical issue, and the existing RAC facility in Raleigh offers a location acceptably convenient for Wake County residents. The proposed TVC ASC would duplicate the RAC service area. The map below shows the primary and secondary service areas (PSA and SSA, respectively) for the two vascular access centers. They share the same PSA in Wake County, while only a few SSA counties are unique to one facility. This again demonstrates that TVC is a redundant and unnecessary project that will not provide a new service, address underserved populations, or solve an unmet need in Wake County.



Source: CON applications Project ID # J-12253-22, p. 38; CON application Project ID # J-111551-18, p. 26.

The Agency's approval of the TVC vascular center would give Wake County two of three licensed vascular ASCs in the entire state. (Azura and its management services subsidiary, AAC Management Services, LLC, would be the operator of all three centers.) No county in North Carolina has two single-specialty vascular access ASCs. The service areas for these facilities are multi-county regions rather than local markets that include specific zip codes. The 2022 SMFP Need Determination includes only two ORs for Wake County. Devoting scarce OR approvals to this type of ASC would waste the opportunity to approve a needed facility in Wake County. Wake County and the surrounding counties in HSAs IV, V, and VI are adequately served by the existing RAC vascular center. Patients in Wake County have reasonable access to the RAC, and the facility has capacity to accommodate utilization growth. The RAC can also complete a cost-effective facility renovation that will add a fourth PR and enable further growth.

For these and other reasons the Agency may identify, the TVC project is non-conforming with Criterion (6) and should not be approved.

CRITERION (12)

(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.

To demonstrate conformity with Criterion (12), the burden rests with the applicant to demonstrate that the cost and design of its proposed project represent "the most reasonable" alternative and will not unduly increase the costs of providing the service. TVC failed to carry its burden. The most reasonable alternative is not to build out a new ASC but for TVA physicians to continue to provide 95% of the procedures projected for TVC in the TVA office and to perform any procedures that require an ASC at the RAC.

TVC is not conforming to Criterion (12) because TVC did not adequately demonstrate that the population proposed to be served has a need for the new construction as proposed. See the 2019 Mecklenburg Acute Care Bed and OR Review, which found Atrium Lake Norman non-conforming to Criterion (12).

For these and others reasons the Agency may discern, the TVC application is not conforming with Criterion (12).

CRITERION (13)

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and … persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services;

Approval of the TVC application will have no benefits for the health-related needs of the elderly or of members of medically underserved groups. All services projected for TVC will be delivered in the TVA offices or at the RAC if the application is denied. Approval of the application will increase the cost of services for all procedures that are now performed in a physician office. Higher costs can mean higher patient responsibility amounts that can cause fixed and low-income patients to delay or forego care, to the detriment of their health. For these and other reasons the Agency may discern, the TVC application is not conforming with Criteria (13)(a) and (13)(c).

CRITERION (18a)

(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.

TVC is owned and controlled by Azura/Fresenius, which owns and controls the RAC, the existing vascular access ASC in Wake County. The TVA proposal offers no beneficial effects of competition for vascular access services.

TVC did not adequately demonstrate how its proposal will promote the cost effectiveness of the proposed services because TVC's projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference.

TVC has not adequately demonstrated how its proposal will promote the cost-effectiveness of the proposed services because TVC does not adequately demonstrate that the financial feasibility of its proposal. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. Consequently, TVC will not enhance competition nor have a positive impact on cost effectiveness, and it has failed to demonstrate conformity with Criterion (18).

For these and other reasons the Agency may discern, the TVC application is non-conforming with Criterion (18a).

PERFORMANCE STANDARDS: 10A N.C.A.C. 14C.2103

(a)	**An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.**
(b)	**The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.**

TVC does not adequately demonstrate the need for the proposed project, or that the projected utilization is reasonable and adequately supported.

TVC's projected utilization is based on a plan to "shift" cases from TVC's office-based vascular center to the proposed ASC. However, when Azura previously sought a CON to establish and later expand a vascular access center, the RAC in Wake County, it projected it would fill that ASC with patients shifting from TVC's office-based vascular center. The same patient population cannot be "double-counted." Therefore, the TVC utilization is not reasonable and adequately supported.

TVC does not show why the population projected to be served has a need to access care at TVC's proposed ASC in Cary when the RAC is available in Wake County and has considerable capacity. Patients can be expected to utilize the RAC in southeast Raleigh, which makes the TVC utilization projections for its proposed center in Cary unreasonable and unsupported.

TVC's projected utilization is questionable because patients can have a range of vascular procedures performed safely by their physicians at TVC's office-based vascular center without incurring extra ASC costs. Patients are cost-conscious and increasingly make informed decisions about their health care, including choosing the most economical sites available to meet their healthcare needs.[26]

[26] TVC's application discusses the important role of health care costs in an "ASC versus hospital" discussion, although that discussion is not supportive of the TVC proposal.

The full discussion regarding analysis of need and projected utilization is found in Criterion (3) and incorporated by reference.

TVC does not provide a reasonable basis for the number of OR procedures it projects. TVC states, "Historically, fistula creations have not been performed in office-based vascular access centers," and notes that some fistula creation patients require additional procedures. On page 136 of its application, TVC projects it will perform 122 fistula creation and related procedures in the OR in its third year. The other procedures can and have been performed in physicians' offices.

Substituting the projected OR cases with the only service not currently being provided in the office-based setting (the fistula creation procedures) reduces the need to 0.11 ORs in year three. This does not meet the performance standard, and TVC does not demonstrate a need for the requested OR.

Surgical Cases	**2024**	**2025**	**2026**
# of C-Sections Performed in Dedicated C-Section ORs			
# of Inpatient Surgical Cases (2)			
# of Outpatient Surgical Cases	**120**	**120**	**122**
Total # of Surgical Cases (2)	120	120	122
Case Times (from Section C, Question 12(c) or 12(d))			
Inpatient			
Outpatient	70.1	70.1	70.1
Surgical Hours			
Inpatient (3)			
Outpatient (4)	140.2	140.2	142.5
Total Surgical Hours	140.2	140.2	142.5
# of ORs Needed			
Group Assignment (5)	6	6	6
Standard Hours per OR per Year (6)	1312	1312	1312
Total Surgical Hours / Standard Hours per OR per Year	**0.11**	**0.11**	**0.11**

Because TVC does not demonstrate the need for the proposed project or that the projected utilization is reasonable and adequately supported, the applicant cannot demonstrate the need for the one new OR based on the OR Need Methodology in the 2022 SMFP. Therefore, the application is not conforming with this rule.

An additional reason exists for finding the TVC application non-conforming to Criterion (3) and the performance standard. TVC cannot be found to have demonstrated its ability to meet the need for new ORs because it provides no evidence in its application as filed that, as of the date of its application, American Access Care of NC ASC, LLC, was an existing entity with legal authority to do business in North Carolina.

Under the CON Law, an applicant can only be required to furnish "that information necessary" to determine its conformity with the applicable review criteria. Stated another way, if the application form provided by the Agency requests information, by statute, that information is legally defined as "information necessary" to show the application's conformity with the review criteria. Section 131E–182 provides:

> *An application for a certificate of need shall be made on forms provided by the Department. The application forms … shall require such information as the Department, by its rules deems necessary to conduct the review. An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under G.S. 131E–183 and with duly adopted standards, plans and criteria.*

N.C. Gen. Stat. § 131E–182.

Section A of the North Carolina CON Application Form asks for the "Legal Name" of the applicant and whether the applicant is "an existing legal entity." If the applicant does not identify itself as an "existing legal entity," it must provide an explanation. Section A elicits information the Agency can use to determine whether the application has been filed by a *bona fide* legal entity capable of carrying out the project proposal.

If this information were inconsequential, a North Carolina CON application could be filed under any name and it would be unimportant that the applicant was not an entity legally capable of carrying out the project proposal if approved. If no question required identification of the applicant entity and its legal status, the Agency (and commenters) would have no basis to question the applicant's ability to meet the need for its project as proposed. Instead, the application asks for the name of a "legal entity" that is "existing," or an explanation. The application, true to North Carolina General Statutes § 131E–182, asks for "that information necessary" to establish the applicant's conformity with the review criteria.

Nothing in the TVC application as filed shows that, at the time of its CON application, American Access Care of NC ASC, LLC, was an existing legal entity authorized to do business in North Carolina. No explanation is provided.

Instead, the information in Exhibit A.1 shows only that American Access Care of NC ASC, LLC, was formed in Delaware in July 2022, with an address in Wilmington, Delaware. Nothing in

Exhibit A.1 establishes that this is an existing entity legally authorized to do business in North Carolina.

A Certificate of Authority (COA) is the legal authorization which a foreign entity must obtain to conduct its affairs in North Carolina. In other words, a COA is what makes a foreign entity "an existing legal entity" that can act in our State. Under North Carolina law, a foreign entity (from another state or country) may not transact business in North Carolina until it obtains a COA from the Secretary of State:

> *A foreign corporation may not transact business in this State until it obtains a certificate of authority from the Secretary of State.*

N.C. Gen. Stat. § 55-15-01.

A foreign corporation may apply for a COA to transact business in this State by delivering an application to the North Carolina Secretary of State for filing. The application must set forth:

(1) The name of the foreign corporation or, if its name is unavailable for use in this State, a corporate name that satisfies the requirements of Article 3 of Chapter 55D of the General Statutes;

(2) The name of the state or country under whose law it is incorporated;

(3) Its date of incorporation and period of duration;

(4) The street address, and the mailing address if different from the street address, of its principal office if any, and the county in which the principal office, if any, is located;

(5) The street address, and the mailing address if different from the street address, of its registered office in this State, the county in which the registered office is located, and the name of its registered agent at that office; and

(6) The names and usual business addresses of its current officers.

The foreign corporation must deliver with the completed application a certificate of existence (or a document of similar import) duly authenticated by the secretary of state or other official having custody of corporate records in the state or country under whose law it is incorporated.

If the North Carolina Secretary of State finds that the application conforms to law, he shall, when all fees have been tendered as prescribed:

(1) Endorse on the application and an exact or conformed copy thereof the word "filed" and the hour, day, month, and year of the filing thereof;

(2) File in his office the application and the certificate of existence (or document of similar import as described in subsection (b) of this section);

(3) Issue a Certificate of Authority to transact business in this State to which he shall affix the exact or conformed copy of the application; and

(4) Send to the foreign corporation or its representative the Certificate of Authority, together with the exact or conformed copy of the application affixed thereto.

N.C. Gen. Stat. § 55-15-03.

The TVC application, as filed, does not show that TVC delivered the necessary documents and the prescribed fee to the North Carolina Secretary of State, nor does it show that the North Carolina Secretary of State received and found sufficient submissions and fees that may have been tendered by TVC. The TVC application shows no evidence that the North Carolina Secretary of State endorsed any TVC filing or issued a COA to TVC to transact business in North Carolina as of the date of TVC's CON application submission to the Agency.

Nothing in the TVC application exists to show that, on the date the CON application was filed, American Access Care of NC ASC, LLC, was an existing entity legally authorized to transact business in North Carolina. Therefore, nothing shows that this applicant can meet the need for its project as proposed. An applicant cannot amend its CON application to include information on a filing it made ***after*** its CON application was submitted to the Agency. The law is simply stated in the North Carolina CON regulations:

An applicant may not amend an application.

10A N.C.A.C. 14C.0204.

North Carolina Courts have uniformly held that an applicant may not amend an application for a CON once the application is deemed complete. See *In re Application of Wake Kidney Clinic*, 85 N.C. App. 639, 643, 355 S.E.2d 788, 790–91, disc. review denied, 320 N.C. 793, 361 S.E.2d 89 (1987); *Presbyterian-Orthopaedic Hosp. v. N. Carolina Dept. of Hum. Res., Div. of Facility Servs., Certificate of Need Section*, 122 N.C. App. 529, 537, 470 S.E.2d 831, 836, writ allowed, 344 N.C. 632, 477 S.E.2d 58 (1996). In the *Presbyterian-Orthopaedic* case, based on Stanley Memorial Hospital's amendment to its application, the Court held it could not be awarded a CON.

Accordingly, TVC cannot now amend its CON application to include information about filings, if any, that American Access Care of NC ASC, LLC, may have made with the North Carolina Secretary of State after it filed its CON application. Any actions constituting an amendment to the TVC application will preclude the award of a CON to TVC.

COMMENTS SPECIFIC TO KM SURGERY CENTER

CRITERION (1)

(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.

Policy GEN-3: Basic Principles

"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."

Although the KM proposal to develop an ASC with one OR and two PRs is consistent with the 2022 SMFP Need Determination, it is not consistent with Policy GEN-3. Therefore, it does not conform to Criterion (1).

The KM application does not demonstrate how its project will promote safety and quality in the delivery of health care services. This is not a typical ASC proposal.

- According to Exhibit A.1, KM Surgery Center, LLC, was created in June 2022 by Dr. Emil Kheterpal. The documents in Exhibit A.1 identify no other persons as members of KM. The applicant is a single urologic surgeon with no documented experience in developing or managing ASCs or facilities providing 23-hour care.
- ASCs are built, equipped, and staffed to perform scheduled, non-urgent surgeries. KM implies it will redirect patients with kidney stones from hospital emergency departments for surgery at the ASC at all hours. Opening an ASC and mobilizing a surgical team and nursing staff at 2:00 a.m. does not suggest high-quality care.
- The proposed ASC is a 14,000-square-foot multi-specialty surgery center proposing to offer 24/7 urology surgical services, with beds for 23-hour patients. The wide range of surgical specialists the applicant projects will use the facility will require an extensive array of equipment and instruments.

- The utilization projections rely on letters of support from a variety of physicians in multiple surgical subspecialties. The projections call for numerous surgeons to each bring a small number of cases to KM. The wide range of procedures and limited case volume means the small KM ASC clinical staff will not have much experience in many of these procedures.
- The KM application does not indicate any plans or any budget in Form F.3b for KM to engage the services of an experienced ASC management company during the development, start-up, or operation of its proposed ASC.

In response to Policy GEN-3, the KM application states that (a) surgeons expected to practice at KM have expertise in performing surgeries in other facilities; and (b) the facility will have quality protocols. Expertise in surgery does not equate to expertise in managing a multi-specialty ASC operating 24/7 and caring for 23-hour patients. The application and the applicant have not established KM can offer safety and quality in delivering the proposed services.

The KM application proposes to provide "urgent and emergent kidney stone treatment" for a potentially high volume of after-hours cases, but it does not document how KM will deliver such care with safety and quality. In the first year, KM budgets for "20%" on-call nursing coverage, which mathematically amounts to 5 hours of coverage for 73 days. This is the equivalent of after-hours surgeries one or two days each week, year-round (e.g., one 5-hour after-hours surgery session every week of the year for 52 weeks, with 21 weeks of the year including two such sessions). In the second and third years, the percentage is increased, showing plans for 109 days of after-hours surgery in Year 2 and 146 days of after-hours surgery in Year 3.

The scenario of 24/7 kidney stone surgery the KM application presents is unrealistic. A patient experiencing abdominal pain in the middle of the night would be unsure whether the pain was associated with a kidney stone, a gallbladder attack, or appendicitis. Most likely, the person would go to a hospital emergency department for diagnosis and possible treatment. It is highly unlikely the patient will know of or call on KM.

In most cases, when an emergency department diagnoses a kidney stone with a CT scan, the patient is unlikely to have immediate surgery. The emergency department will either call an on-call urologist or refer the patient to a urologist for a follow-up visit. The urologist will determine whether lithotripsy or surgery is the best way to treat the kidney stone. Lithotripsy is the most common treatment for kidney stones in the United States.[27] In the short term, pain can often be controlled with medication. If needed, most surgeries can be scheduled. If the patient needs urgent or emergent kidney stone surgery, it would best be done at the hospital where the patient presents. A hospital is equipped and staffed for emergency surgery with on-call surgeons and hospital-based

[27] National Kidney Foundation. Kidney Stone Treatment: Shock Wave Lithotripsy. Available at: https://www.kidney.org/atoz/content/kidneystones_shockwave

physicians, a 24-hour pharmacy, and the ability to care for the patient post-surgery in an observation or inpatient bed.

It is difficult to see how transferring the patient from a hospital with an organized on-call surgical team, support services, and post-surgery nursing services to a closed ASC would be in the best interest of the patient. This proposal raises safety and quality concerns not addressed by the applicant:

- How is the patient transported to the ASC and what cost does that add?
- How are patients admitted to the ASC after hours with no administrative staff?
- Does KM have anesthesia coverage for the unscheduled 24/7 surgeries? When an anesthesia group agrees to provide coverage for an ASC, it reasonably expects the coverage is on weekdays, about eight hours per day. The letter from ECAA Anesthesia Specialists (ECAA) in Exhibit I.1 does not state that ECAA will provide on-call after-hours anesthesia. Absent explicit language in a letter or contract, it is unreasonable to assume an anesthesia group has agreed to provide anesthesia on-call, 24/7, with no payment for on-call time.
- What pharmacy staff is available to dispense medications?
- How will surgical instrumentation trays be prepared after hours with no instrument/ sterile processing staff?
- If patients are to be kept 23 hours, how will their dietary needs be met?

The KM application fails to explain how it can offer safety and quality in delivering OR services as proposed. Thus, it fails to show conformity with Policy GEN-3 and Criterion (1).

In response to Policy GEN-3, KM states it will provide 24/7 urology surgery to decrease patient use of narcotics and opioids and to decrease ER visits. These statements lack logical support. Even if KM is approved, most patients would likely be diagnosed and treated just as they are now. A patient in acute pain will be prescribed pain management medication and scheduled for diagnostic imaging to confirm the presence of a stone, after which the patient's physician will determine whether surgery or lithotripsy is appropriate. Nothing suggests that KM will change this process or the associated timing.

As indicated on page 38 of the KM application, KM envisions that patients arriving at its proposed ASC for a kidney stone procedure will "already have a documented stone." A kidney stone is commonly confirmed with a CT scan. There is no CT scanner proposed at KM. If the patient had not already been to a hospital and received a CT scan, he/she would have to leave KM and go to a hospital, presumably with appropriate medications for pain control.

Even for non-emergent patients being monitored for kidney stones, the KM application does not explain how the option to ultimately have a kidney stone procedure at KM in lieu of another site of service in Wake County will affect the patient's need for pain management medications or change the possibility that the patient will visit a hospital ER.

Nothing in the KM application documents that patients will use narcotics or opioids for a shorter time if the KM proposal is developed. If a patient has a documented kidney stone and requires a procedure to remove it, KM has presented nothing to show that area facilities cannot accommodate the timely scheduling and performance of such a procedure, whether emergent or not. The physicians who intend to perform surgeries at KM already provide kidney stone procedures at area facilities, and none indicated they must keep their patients on pain medication for an extended period because of lack of access to an area facility.

The KM application states an intent to offer equitable access. It does not, however, document how its proposed ASC will enhance patient access. KM presents no documentation showing that patients who need kidney stone procedures cannot timely access those services in Wake County now.

For these reasons and any others the Agency may discern, the KM application fails to document conformity with Policy GEN-3 and thus with Criterion (1). Absent conformity with Criterion (1), the Agency cannot approve the KM application.

CRITERION (3)

(6) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

An applicant must present reasonable and adequately supported utilization projections to show need for the proposed project. If projected utilization is not reasonable or is inadequately supported, the application is not conforming with Criterion (3). KM is primarily based on the need to offer 24/7 urgent and emergent kidney stone surgery to reduce the use of pain medication and reduce ER visits. For the reasons stated here and as to Criterion (1) above, the KM application fails to adequately support the stated need.

KM argues the need for its center by citing the annual number of emergency department (ED) visits in Wake County by patients with a diagnosis of kidney, ureter, or urinary stone. KM cites

Truven data which indicate that between 1,283 and 1,918 stone patients have visited Wake County EDs each year from 2017 to 2021.

However, KM does not use Truven data or other sources to document the treatment options that follow kidney stone diagnosis. Therefore, it does not establish the need for an ASC focusing on urologic surgery. Of the 1,200 to 1,900 annual ED patients:

- How many pass the stone without surgery?
- How many are treated with lithotripsy and without surgery?
- How many have surgery?
- How many have surgery at the hospital in connection with the ED visit?
- For those who require surgery, how many area facilities with ORs already offer stone surgeries?
- Is there any lag in the ability to schedule stone surgeries?
- Will KM offer any equipment in its OR that other area surgical facilities do not offer?

Shock Wave Lithotripsy (SWL) is the most frequent treatment option for kidney stones. In and around Wake County, the State Medical Facilities Plan shows multiple locations offering lithotripsy, including Duke Raleigh Hospital, Rex Surgery Center of Cary, WakeMed, Durham Ambulatory Surgery Center, Nash Day, NC Specialty Hospital, and Rex Hospital. The KM application does not propose to offer a lithotripter (which requires a separate CON), nor does it discuss Truven or other data on the number of patients with a stone diagnosis who receive surgery or SWL.

KM is not proposed as a single-specialty urology center and does not argue that its facility will offer unique attributes unavailable at existing surgical sites. Instead, KM will be another multi-specialty ASC, like all other ASCs where stone surgeries may now be performed in Wake County.

KM presents no data or physician letters documenting kidney stone surgery in Wake County is being delayed due to lack of properly equipped ORs. KM does not present data on the length of time surgeons must wait to schedule patients for stone surgeries.

Because KM does not address the above questions and issues, the data on stone patients served in area EDs do not document a need for KM.

KM cites a Massachusetts study[28] on the number of ER visits associated with “renal colic” and the incidence of subsequent kidney stone procedures. The study states that patients may be prescribed opioid pain medication between the ED visit and the kidney stone procedure. Nothing in the KM

[28] See page 36 of KM’s application, which refers to “A Massachusetts Emergency Department retrospective cohort study performed in 2019.”

application explains how the KM will affect the frequency of prescription of opioid medications to pain-impacted patients in hospital ERs. Nothing in the KM application explains how the KM will affect the time between diagnosis of a kidney stone, determination that surgery is required instead of lithotripsy, and the scheduling of kidney stone surgery.

Other studies cited by KM[29] indicate that patients prescribed opiates in the ED may require a refill of those prescriptions before the resolution of a kidney stone episode. This study says nothing about how a facility like the KM would affect prescribing protocols or the scheduling of kidney surgery.

Another study cited by KM[30] notes that ED visits for renal colic episodes are often costly because 83% of patients have a CT scan in the ED. KM will not have a CT scanner. KM proposes some diagnostic imaging equipment, but nothing suggests that ED patients will be transported from the hospital to KM in an emergent renal colic episode to receive non-CT imaging. Such a transfer scenario is highly improbable. Thus, approving KM will not affect the number of patients in Wake County who receive a CT scan to confirm a kidney stone in an ED. Nothing in the cited study supports a finding of need for KM. The application did not explain how the study supports the projected volume of urology procedures.

It is highly unlikely that patients experiencing after-hours abdominal pain would present at KM for an emergency kidney stone procedure. Nothing indicates the average Wake County resident would know about KM, would know they were having a kidney episode as opposed to some other form of emergency medical need, or would elect to go to a closed surgery center during a chronic pain episode. Even if such a patient were to go to KM, absent a CT scan or other documented evidence of a kidney stone, it is highly improbable the patient would receive an immediate emergency kidney stone procedure at KM.

For existing patients of the urology physicians supporting the KM application, nothing is provided to explain why those physicians cannot already make prescribing decisions to manage their patients' use of pain medications between diagnosis and a kidney stone procedure. KM does not document how the availability of KM will reduce the use of narcotic pain medication.

KM Failure to Demonstrate Need for Its Proposed ASC Given Other Comparable Capacities

KM describes its selected site for KM as near both the Triangle Surgery Center and the WakeMed Brier Creek Emergency Department. Triangle Surgery Center, at 7921 ACC Boulevard, is the facility previously known as Triangle Orthopaedics Surgery Center (TOSC). TOSC was developed under a need determination in the 2010 State Medical Facilities Plan (SMFP) for a single-specialty

[29] See pages 36-37 of KM's application. No citation are provided, but five studies are referenced .
[30] See KM's Exhibit C-1. Schoenfeld, Elizabeth et al. 2019. Association of Patient and Visit Characteristics with Rate and Timing of Urologic Procedures for Patients Discharged from the Emergency Department with Renal Colic. *JAMA Network Open*. 2019;2 (12).

ambulatory surgery demonstration project. However, in 2019, TOSC applied and was subsequently CON approved to add OR capacity and convert from a single specialty to a multi-specialty center, adding pain management, general surgery, and plastic surgery. On December 7, 2020, TOSC changed its name to Triangle Surgery Center.

Triangle Surgery Center has three ORs and was approved to add two PRs in 2019, without CON review. See Exhibit I. It can offer general surgery, plastic surgery, and pain management, three of the specialties proposed for KM. Triangle Surgery Center is adjacent to the KM site. The two are only separated by a utility easement. Triangle Surgery Center is not affiliated with any area hospital/health systems and can offer patients the advantages associated with care in a lower-cost ASC setting.

The KM application offers no reason physicians other than urologists would choose KM over Triangle Surgery Center for pain management, general surgery, or plastic surgery procedures. Nothing in the KM application suggests physicians cannot obtain OR time for these procedures at Triangle Surgery Center. KM does not propose to offer patients specialized equipment or expertise or an enhanced patient experience beyond what can reasonably be expected to be offered at Triangle Surgery Center. Considering patients can get pain management, general surgery, and plastic surgery at a nearby existing ASC that appears to offer care equivalent to KM's, there is no support for the need for such services to be offered at KM.

Unsupported and Unreasonable Utilization Assumptions

KM's projections are not reasonable and adequately supported. KM presents utilization assumptions and calculations that, like other application sections, require deciphering, given the minimal narrative accompanying the tables. When examined, the assumptions KM used are illogical and unreasonable.

The physician letters indicate the volume of procedures those physicians potentially could perform at KM. KM's utilization is built on a patently unreasonable premise under which a variety of surgeons will each perform a *very small* number of surgeries at KM. As a practical matter, it is unreasonable to assume over a dozen doctors will travel to a center, become comfortable with its equipment and staff, and perform only one to three OR cases and a few PR cases each week.

For example, Dr. Baker indicates a historical volume of 290 cases, with 240 being ASC appropriate. He projects he "could" perform all 240 cases at KM, with 96 in the OR and 144 in a PR. But KM projects Dr. Baker will shift only 40% of his ASC-appropriate cases to KM in Year 1. As a practical matter, this creates a Year 1 scenario under which Dr. Baker will perform only 38 OR cases (40% of 96) and 58 PR cases (40% of 144) at KM. This would mean he would do

less than 1 OR case each week at KM and only 1 or 2 PR cases at KM each week throughout the first year. This would be highly inefficient for Dr. Baker, and thus highly unlikely.[31]

Nothing indicates the numerous supporting urologists were informed that KM expects them to perform only 40% of their ASC-appropriate cases at KM in Year 1. Only after deciphering the numbers can one discern that the utilization forecasts for KM essentially have a broad array of urologists purportedly agreeing to bring an inefficiently small number of weekly cases to KM. Mathematically, KM is projected to be used by 15 urologists, with none performing more than about 1 to 3 OR cases per week in Year 1. Nothing in KM's narrative explains this, nor is it specified in the physician letters.

In responding to the above comments, KM could suggest its utilization will likely be much higher than it has forecasted, given the overall volume of what KM describes as "available" cases. This is not an effective response because an applicant must present a CON application that demonstrates need and financial feasibility grounded on reasonable and adequately supported assumptions. Obviously, if KM had projected different (i.e., higher) utilization, it would have had to project more staff, more supply expenses, etc. It would have had to identify the assumptions associated with the need for a center providing more cases and support for its ability to provide a specific, higher number of cases. It did none of this. Thus, it cannot answer for unreasonable projections by suggesting it could have made different projections that were not set forth or supported within the four corners of its application. Nor can it now amend its application to set out different projections or different assumptions.

Similarly, for non-urology cases, 885 non-urology OR cases are shown as "available," but only 20% (or 177) of such cases are expected to be performed at KM in Year 1. In the ophthalmology specialty, for example, KM suggests 200 eye OR cases are "available" and an increasing number of such cases will be performed each year. The KM ophthalmology cases are based on volumes described by one physician, Dr. Jindal. Effectively, KM assumes Dr. Jindal will perform the following number of OR cases at KM:

Eye Cases Available	Year 1: 20% to KM	Year 2: 30% to KM	Year 3: 40% to KM
200	40	60	80

The very low number of ophthalmic procedures forecasted for KM raises numerous questions which call into doubt the reasonableness of the assumptions underlying the projections. While it is possible a physician or physician group will want to use KM to ease access concerns or allow for more prompt scheduling of cases, Dr. Jindal does not express such intentions in his letter.

[31] Presumably, this doctor would then have to perform 50 cases in a hospital setting and another 144 cases somewhere else.

The application does not document it will be reasonable and cost-effective for KM to outfit its surgery center with specialized equipment for cataract and other eye surgeries if only a single physician is expected to perform no more than one to two eye surgeries at KM each week. KM's equipment list shows no femtosecond laser, which is important medical equipment for sophisticated cataract surgeries.

The application does not document it will be reasonable and cost-effective for KM to attract, train, and retain OR nurses with special talent in ophthalmic surgeries, given its plan to offer only one to two such OR cases each week. Will eye surgeries performed at KM be supported by professionals who are not specially trained or frequently performing OR eye surgery cases? If so, do the KM projections raise questions about the applicant's documentation of safety and quality in delivering these services?

The application does not document it will be reasonable for an eye surgeon to travel to KM each week to perform only one OR eye case. Providing on average one OR ophthalmic case (or less) per week does not materially increase access to ophthalmic surgery for Wake County residents. KM Surgery Center is unlikely to be an ASC "of choice" for patients when deciding on a site of service for surgeries affecting their eyesight. KM Surgery Center will not be outfitted to provide a full range of procedures, including femtosecond laser procedures. It is doubtful the center will attract patients for ophthalmic surgeries.

For other specialties, the dynamics are similar. KM projects low-volume utilization in non-urology specialties, making it doubtful the center will be a first-choice option for patients requiring these types of surgical care.

For these reasons and such others as the Agency may discern, the KM application is not conforming with Criterion (3).

CRITERION (4)

(7) 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.

KM did not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need, based on the following:

- KM does not document the need for its proposed project, or that projected utilization is reasonable and adequately supported. See the discussions about need and projected utilization under Criterion (3) above. A project that is unnecessary and does not provide

reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.

- KM does not document the project is financially feasible. See the discussion regarding financial feasibility under Criterion (5) below. A project that is not financially feasible is not the most effective alternative to meet the need.
- KM does not document the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. See the discussion about unnecessary duplication under Criterion (6) below. A project that is unnecessarily duplicative cannot be the most effective alternative to meet the need.
- TVC did not provide credible information to explain why it believes its proposed project is the most effective alternative.
- Based on the information in the application as filed, the least costly and most effective alternative would likely be a single-specialty urology ASC providing scheduled urology procedures and no 24/7 surgery or 23-hour patient beds. If the applicant decided on a multi-specialty ASC, the least costly and most effective alternative would be an ASC for a narrower range of specialties to reduce the equipment costs and increase the efficiency of the staff and physicians by performing a higher volume of a narrower range of procedures.
- KM is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

For these reasons and such others as the Agency may discern, the KM application is not conforming with Criterion (4).

CRITERION (5)

(8) 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.

KM's projected utilization is not reasonable and adequately supported for all the reasons discussed above under Criterion (3). As projected revenues and expenses are based at least in part on projected utilization, KM's projected revenues and expenses are also questionable, rendering the KM application non-conforming to Criterion (5). See the Criterion (3) discussion above.

Further, the KM application is non-conforming with Criterion (5) because:

- It fails to properly demonstrate financial feasibility in its Section Q Forms.
- It fails to document the availability of funds.
- It fails to document the project is financially feasible, based upon reasonable assumptions about the costs of and charges for providing health services by the person proposing the service.

Failure to Properly Demonstrate Financial Feasibility in Section Q Forms

The CON application form explicitly instructs that "ASFs should complete the revenues and operating costs forms for ORs, GI endo rooms, procedure rooms and the entire facility." KM failed to do so. KM only presents Form F.2b, Projected Revenues and Net Income, and Form F.3b, Projected Operating Costs for the entire facility. KM provides no information in its assumptions and methodology pages that provides insight into the revenues or expense split in the OR v PRs. In doing so, KM does not provide the Agency with adequate information to determine the OR-related revenues and expenses. KM fails to present the financial feasibility of the CON-reviewable OR.

Failure to Properly Demonstrate Availability of Funds

Criterion (5) requires an applicant to "demonstrate the availability of funds for capital … needs." Based on Section 5 and Dr. Kheterpal's letter, in addition to the $9,876,942 obtained through a commercial loan with Wells Fargo, KM will require additional funding of $695,000. Those additional funds are intended to come from AP Shoppes, LLC. The Agency determines the availability of funds for the project "from the entity responsible for funding, which may or may not be an applicant."[32] Even if the Agency were to conclude that the Lease Term Sheet shows a *commitment* by AP Shoppes, LLC to afford KM an upfit allowance of $695,000, the problem is that neither this Lease Term Sheet nor anything else in the KM application exists to document the *availability* of $695,000 in funds. KM does not provide a letter from AP Shoppes, LLC documenting that it will have available $695,000 in funds, nor are there any financial statements or other records to show that AP Shoppes, LLC will have available *any* sum-certain in funds and certainly nothing to show that it will have available $695,000 in funds reasonably likely to be available when needed. Thus, the KM application does not "demonstrate the availability of funds" or conformity with Criterion (5).

The KM application fails to document the availability of sufficient funds for capital and operating needs. Based on the information in its application, KM will experience a significant cash shortfall

[32] Ret. Villages, Inc. v. N. Carolina Dep't of Hum. Res., 124 N.C. App. 495, 498–99, 477 S.E.2d 697, 699 (1996); Blue Ridge Healthcare Hosps. Inc. v. N.C. Dep't of Health & Hum. Servs., 255 N.C. App. 451, 463, 808 S.E.2d 271, 279 (2017) ("application [must] separately document[] the availability and commitment of funds").

in the first operating year. To show sufficient funds for the project, KM needed to identify sources sufficient to cover all capital and operating needs of its proposed project. It did not do so. The only sources of funds KM identified are those shown in the table below. Adding other sources of funds now would be an impermissible amendment to the application.

KM Financial Shortfall

	Pre-Opening and Year 1	Year Two	Year Three
Sources of Cash			
Capital Cost Loan	$9,876,942		
Upfit Allowance	695,000		
Working Capital Loan	1,439,618		
Year One Revenue *1	4,413,373	5,822,105	6,977,691
Total Sources of Cash	$16,424,933	$5,822,105	$6,977,691
Uses of Cash			
Capital Costs	$10,571,942		
Start-up Costs	439,618		
Operating Costs	4,619,966	4,890,189	5,076,781
Principal Payment of Capital Coast Loan	761,708	804,674	850,064
Principal Payment on Working Cap. Loan	1,439,618		
Less Non-Cash Depreciation	-$739,270	-$739,270	-$739,270
Total Uses of Cash	17,093,582	$4,955,593	$5,187,575
Net Cash Flow for the Period	**-$668,648**	$866,512	$1,790,116
Accumulated Cash Balance	-$668,648	$197,863	$1,987,980

** 30-day lag in collections*

The table above shows that the monies KM will have via loan proceeds and ASC revenues will result in a Year 1 shortfall of $668,648. In other words, KM will have $668,648 less than what it needs for the capital and operating expenses and interest/loan repayments it identified in its application for Year 1.

While, "on paper," KM projects to earn money in Years 2 and 3, it has no way to stay "in business" after Year 1 because it has no identified source of funds to pay the obligations described in its application. As a practical matter, this shortfall means that within its first year of operation, KM will run out of money; KM will be without sufficient funds to make payroll for its staff and pay its

obligations to Wells Fargo. KM has not demonstrated short-term or long-term financial feasibility because it will be over $660,000 short of cash to meet its project-related needs by the close of Year 1.

The shortfall is due to KM's identified capital and operating needs, together with the interest and principal payments shown on the loan amortization schedules in its application. KM cannot now "disavow" the intentions indicated in the amortization schedules in its application as to principal repayments. The interest rate assumptions incorporated in the applicant's schedules are based on the principal repayment assumptions imbedded in the amortization schedules.[33]

Understated Medical Supplies Expense

It appears KM made a significant omission when projecting medical supply expense. KM defined a per-case cost of $525 for medical supplies (increasing annually). Yet, as shown below, KM only calculated medical supplies expenses for its OR cases, completely omitting any medical supply expenses for its over 2,000 annual PR cases.

Form F.3b is intended to show Operating Costs for the entire "KM Surgery Center." The Form F.3b Expense Assumptions indicate medical supplies are "estimated based on a per case expense," and a separate table identifies an assumption of $525 to $557 per case across the initial years, as shown below.

Form F.3b Projected Operating Costs upon Project Completion			
Assumptions	1st Full FY	2nd Full FY	3rd Full FY
Salaries from Form H Staffing			
On-Call Wages from Form H Staffing			
Taxes and Benefits as a % of Salaries	23.0%	23.0%	23.0%
Medical Supplies per Case	$525	$541	$557

Expense Using OR Cases x "Per Case" Assumption	*Expense Identified on Form F.3b*
Year 1 OR Cases = 825 X $525 = $433,125	$432,915
Year 2 OR Cases = 994 x $541 = $537,754	$537,533
Year 3 OR Cases = 1,164 x $557 = $648,348	$648,038

[33] The Applicant's projected operating costs in Years 1–3 assume a Wells Fargo loan amount of $9,987,942. The Applicant shows $348,868 in interest during construction, with no principal payments before opening. The interest during construction is shown as a capital cost on Form F.1a. In Year 1, the Applicant uses an interest expense assumption of $565,234, which is a sum of interest on the capital cost loan of $523,960 plus interest on the working capital loan of $41,274. Beginning with Year 1 and moving forward, the Applicant includes interest expense as an operating cost, using the principal repayment assumptions shown in its application.

(The small differences ($210, $221, and $310) each year are likely due to rounding, as the assumed cost per case is $525 but the imputed cost per case ($432,915 / 824 cases) is actually $524.75, which rounds to $525.)

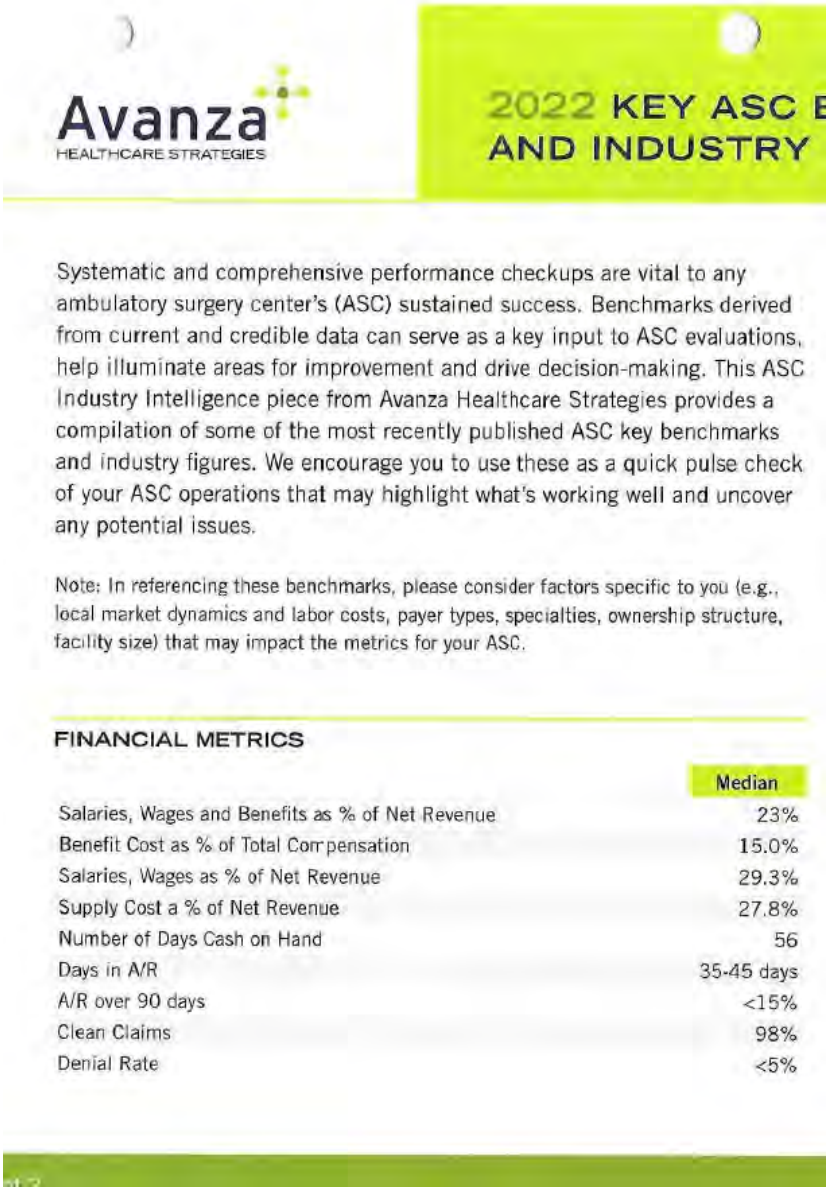
In other words, KM assumed $525 per case for medical supplies but multiplied out that per-case cost by *only* its OR cases. It did not multiply the $525 per-case assumption by the number of PR cases planned for its ASC.

The medical supply expenses are unreasonable and inadequately supported, as it is unreasonable to assume no medical supply expenses for procedures in the two PRs. Moreover, this is inconsistent with KM's approach for other expense categories:

- For linen expenses, KM projects $14.00 per case in Year 1, increasing slightly each year. For this expense, KM multiplied the per-case cost by both its OR and PR cases, using the same per-case assumption for both types of rooms.
- For insurance costs, KM projected $10,500 plus a "per case" assumption of $15.00 in Year 1, increasing each year. Again, KM multiplied the per-case cost by both its OR and PR cases, using the same per-case insurance cost assumption.

These examples show that, except for its mistake as to medical supplies: (1) KM identified total expenses by multiplying per-case values by ***both*** OR and PR cases; (2) KM used the same per-case assumptions for OR and PR cases. KM used a uniform "per case" assumption across both OR and PR cases, except for medical supplies.

The apparent error with the medical supply cost projection is evident when comparing KM's projection to the benchmark report from Avanza that KM included as Exhibit C.4. Page 1 of the Avanza report shows several "benchmarks" as a reference or "pulse check" for ASCs. Avanza suggests, for example, that a Salary/Wage/Benefit projection should be approximately 23% of an ASC's net revenue. KM made a Salary/Wage/Benefit projection generally in line with the Avanza benchmark at approximately 25.6% of net revenue (see below). While Avanza suggests a Supply Cost benchmark at 27.8% of net revenue, however, KM remarkably projects medical supply expenses at only 9.2% of net revenue.



Avanza
HEALTHCARE STRATEGIES

2022 KEY ASC E
AND INDUSTRY

Systematic and comprehensive performance checkups are vital to any ambulatory surgery center's (ASC) sustained success. Benchmarks derived from current and credible data can serve as a key input to ASC evaluations, help illuminate areas for improvement and drive decision-making. This ASC Industry Intelligence piece from Avanza Healthcare Strategies provides a compilation of some of the most recently published ASC key benchmarks and industry figures. We encourage you to use these as a quick pulse check of your ASC operations that may highlight what's working well and uncover any potential issues.

Note: In referencing these benchmarks, please consider factors specific to you (e.g., local market dynamics and labor costs, payer types, specialties, ownership structure, facility size) that may impact the metrics for your ASC.

FINANCIAL METRICS

	Median
Salaries, Wages and Benefits as % of Net Revenue	23%
Benefit Cost as % of Total Compensation	15.0%
Salaries, Wages as % of Net Revenue	29.3%
Supply Cost a % of Net Revenue	27.8%
Number of Days Cash on Hand	56
Days in A/R	35-45 days
A/R over 90 days	<15%
Clean Claims	98%
Denial Rate	<5%

	Avanza Suggested Benchmark[34] (% of Net Revenue)	**KM Projections**
Salaries/Wages/Benefits	**23%**	**25.6%**
Supplies	**27.8%**	**9.2%**

[34] Another published benchmark for ASC supply cost is from BeckersASC.com. This source estimates that a reasonable ASC per-case assumption would be approximately $456 per case for drugs and medical supplies, as of 2019.[34] With adjustments for inflation, this is reasonably close to the $525 per-case assumption KM used on Form F.3b for the first full FY on page 137.

KM likely made a reasonable per-case assumption for its medical supply expense; it simply did not apply that per-case assumption to both its OR and PR cases. As a result, its medical supply expense assumption for its entire facility is dramatically understated and, if correctly included, would markedly affect KM's financial demonstrations.

To estimate the potential magnitude of this error, we recast the required financial forms, Form F.2b, Projected Revenues and Net Income Upon Project Completion, and Form F.3b, Projected Operating Costs Upon Project Completion, for two scenarios. The first scenario assumed medical supply expense for PR cases was the same as for OR cases (starting at $524.75). The second scenario assumed a per-case medical supply expense for PR cases at half the expense for OR cases (starting at $262.37 per case.).

The table below shows the results. At the full cost per case scenario, KM will not break even for the three-year period; it will have an accumulated loss of $915,297. Even using a per-case medical supply assumption that is 50% of per-case assumption for OR cases, KM omitted over $2 million in supply costs.

The underestimation of medical supply expenses significantly affects the cash-flow shortfall presented earlier. This has been recast in tables following Form F.2b and F.3b. The cumulative cash shortfalls for the three-year period are as high as $2.1 million under the full cost scenario. Even in the second scenario, cumulative cash flow is negative at the end of Year 3. The KM application does not document financial feasibility using reasonable medical supply cost assumptions.

Form F.2b Including Medical Supply Cost Per Case for Both OR & PR Cases

Form F.2b Projected Revenues and Net Income Upon Project Completion	**1st Full FY**	**2nd Full FY**	**3rd Full FY**
	F: mm/dd/yyyy	F: mm/dd/yyyy	F: mm/dd/yyyy
OP Surgery, KM Surgery Center	2025	2026	2027
Patient Services Gross Revenue			
Self-Pay	$303,499	$363,275	$426,365
Insurance *	10,722,616	13,027,824	15,461,694
Medicare *	4,832,773	6,040,624	7,316,597
Medicaid *	286,849	390,366	499,836
Other (Specify)	530,303	660,873	798,800
Total Patient Services Gross Revenue	$16,676,040	$20,482,962	$24,503,292
Other Revenue (1)			
Total Gross Revenue (2)	$16,676,040	$20,482,962	$24,503,292
Adjustments to Revenue			
Charity Care	$807,320	$991,620	$1,186,252
Bad Debt	345,994.00	424,980.00	508,394.00
Contractual Adjustments	10,708,137.00	13,152,665.00	15,734,228.00
Total Adjustments to Revenue	$11,861,451	$14,569,265	$17,428,874
Total Net Revenue (3)	$4,814,589	$5,913,697	$7,074,418
Total Operating Costs (from Form F.3)	$5,752,891	$6,263,223	$6,701,887
Net Income (4)	($938,302)	($349,526)	$372,531
		Three-Year Accumulation	($915,297.53)

Form F.2b Including Medical Supply Cost Per Case for OR Cases & at 50% for PR Cases

Form F.2b Projected Revenues and Net Income Upon Project Completion	**1st Full FY**	**2nd Full FY**	**3rd Full FY**
	F: mm/dd/yyyy	F: mm/dd/yyyy	F: mm/dd/yyyy
OP Surgery, KM Surgery Center	2025	2026	2027
Patient Services Gross Revenue			
Self-Pay	$303,499	$363,275	$426,365
Insurance *	10,722,616	13,027,824	15,461,694
Medicare *	4,832,773	6,040,624	7,316,597
Medicaid *	286,849	390,366	499,836
Other (Specify)	530,303	660,873	798,800
Total Patient Services Gross Revenue	$16,676,040	$20,482,962	$24,503,292
Other Revenue (1)			
Total Gross Revenue (2)	$16,676,040	$20,482,962	$24,503,292
Adjustments to Revenue			
Charity Care	$807,320.00	$991,620.00	$1,186,252.00
Bad Debt	345,994.00	424,980.00	508,394.00
Contractual Adjustments	10,708,137.00	13,152,665.00	15,734,228.00
Total Adjustments to Revenue	$11,861,451	$14,569,265	$17,428,874
Total Net Revenue (3)	$4,814,589	$5,913,697	$7,074,418
Total Operating Costs (from Form F.3)	$5,186,429	$5,576,706	$5,889,334
Net Income (4)	($371,840)	$336,991	$1,185,084
		Three-Year Accumulation	$1,150,235.23

Form F.3b Including Medical Supply Cost Per-Case for Both OR & PR Cases			
Form F.3b Projected Operating Costs Upon Project Completion **OP Surgery, KM Surgery Center**	**1st Full FY** F: mm/dd/yyyy 2025	**2nd Full FY** F: mm/dd/yyyy 2026	**3rd Full FY** F: mm/dd/yyyy 2027
Salaries (from Form H Staffing)	$1,212,080	$1,358,776	$1,399,539
On-Call Wages	45,625	68,438	91,250
Taxes and Benefits	278,778	312,518	321,894
Medical Supplies	432,915	537,533	648,038
Medical Supplies for Procedure Rooms*	1,132,925	1,373,034	1,625,106
Linen	41,768	50,945	60,636
Central Office Overhead	-	-	-
Professional Fees	-	-	-
Management Fees	-	-	-
Other Fees (specify)	225,000	231,750	238,703
Equipment Maintenance (2)	220,317	220,317	220,317
Utilities	120,000	123,600	127,308
Insurance	54,751	64,584	74,967
Interest Expense	565,234	480,994	435,603
Equipment Taxes	55,079	55,079	55,079
Property and Other Taxes (except Income)	55,079	55,079	55,079
Depreciation - Buildings	281,637	281,637	281,637
Depreciation - Equipment	440,633	440,633	440,633
Depreciation - Furniture	17,000	17,000	17,000
Facility Lease	574,070	591,306	609,098
Total Expenses	$5,752,891	$6,263,223	$6,701,887
* Full Cost Per Case	$525	$541	$557
Number of Cases	2,159	2,539	2,919

Form F.3b Including Medical Supply Cost Per-Case for OR Cases & at 50% for PR Cases

Form F.3b Projected Operating Costs Upon Project Completion **OP Surgery, KM Surgery Center**	**1st Full FY** F: mm/dd/yyyy 2025	**2nd Full FY** F: mm/dd/yyyy 2026	**3rd Full FY** F: mm/dd/yyyy 2027
Salaries (from Form H Staffing)	$1,212,080	$1,358,776	$1,399,539
On-Call Wages	45,625	68,438	91,250
Taxes and Benefits	278,778	312,518	321,894
Medical Supplies	432,915	537,533	648,038
Medical Supplies for Procedure Rooms*	566,463	686,517	812,553
Linen	41,768	50,945	60,636
Central Office Overhead	-	-	-
Professional Fees	-	-	-
Management Fees	-	-	-
Other Fees (specify)	225,000	231,750	238,703
Equipment Maintenance (2)	220,317	220,317	220,317
Utilities	120,000	123,600	127,308
Insurance	54,751	64,584	74,967
Interest Expense	565,234	480,994	435,603
Equipment Taxes	55,079	55,079	55,079
Property and Other Taxes (except Income)	55,079	55,079	55,079
Depreciation - Buildings	281,637	281,637	281,637
Depreciation - Equipment	440,633	440,633	440,633
Depreciation - Furniture	17,000	17,000	17,000
Facility Lease	574,070	591,306	609,098
Total Expenses	$5,186,429	$5,576,706	$5,889,334
*Half Cost Per Case	$262	$270	$278
Number of Cases	2,159	2,539	2,919

KM Shortfall Including Medical Supply Cost Per-Case for Both OR & PR Cases

	Pre-Opening and Year 1	Year Two	Year Three
Sources of Cash			
Capital Cost Loan	$9,876,942		
Upfit Allowance	695,000		
Working Capital Loan	1,439,618		
Year One Revenue *1	4,413,373	5,822,105	6,977,691
Total Sources of Cash	$16,424,933	$5,822,105	$6,977,691
Uses of Cash			
Capital Costs	$10,571,942		
Start-up Costs	439,618		
Operating Costs	5,752,891	6,263,223	6,701,887
Principal Payment of Capital Coast Loan	761,708	804,674	850,064
Principal Payment on Working Cap. Loan	1,439,618	-	-
Less Non-Cash Depreciation	(739,270)	(739,270)	(739,270)
Total Uses of Cash	$18,226,507	$6,328,627	$6,812,680
Net Cash Flow for the Period	**-$1,801,574**	**-$506,523**	$165,011
Accumulated Cash Balance	-$1,801,574	-$2,308,096	**-$2,143,086**

** 30-day lag in collections*

KM Shortfall Including Medical Supply Cost Per-Case for OR Cases & 50% for PR Cases

	Pre-Opening and Year 1	Year Two	Year Three
Sources of Cash			
Capital Cost Loan	$9,876,942		
Upfit Allowance	695,000		
Working Capital Loan	1,439,618		
Year One Revenue *1	4,413,373	5,822,105	6,977,691
Total Sources of Cash	$16,424,933	$5,822,105	$6,977,691
Uses of Cash			
Capital Costs	$10,571,942		
Start-up Costs	439,618		
Operating Costs	5,186,429	5,576,706	5,889,334
Principal Payment of Capital Coast Loan	761,708	804,674	850,064
Principal Payment on Working Cap. Loan	1,439,618	-	-
Less Non-Cash Depreciation	(739,270)	(739,270)	(739,270)
Total Uses of Cash	$17,660,044	$5,642,110	$6,000,128
Net Cash Flow for the Period	**-$1,235,111**	$179,995	$977,564
Accumulated Cash Balance	-$1,235,111	-$1,055,117	**-$77,553**

** 30-day lag in collections*

For the reasons noted above, KM fails to include reasonable and adequately supported assumptions as to expenses. KM also fails to project revenues using reasonable and adequately supported assumptions.

KM Payor Mix Assumptions

KM's payor mix percentages are unreasonable because they are inconsistent with the representations made on page 57 of the KM application about the percentage of total patients within specific demographic groups. That table is reproduced here:

Group	Estimated Percentage of Total Patients During the Third Full Fiscal Year
Low-income persons	5.0%
Racial and ethnic minorities	25.0%
Women	52.0%
Persons with disabilities	8.0%
Persons 65 and older	50.0%
Medicare beneficiaries	29.5%
Medicaid recipients	1.9%

KM states Medicare will cover only 29.5% of total patients in Year 3. Elsewhere, KM states 50.0% of patients in Year 3 will be age 65 and older and therefore Medicare eligible (KM app., pp. 57 & 101). Except for some plastic surgery, one would expect almost all procedures for patients 65 and older to be covered by Medicare. While some individuals over 65 have commercial or other insurance, KM offers no explanation as to why the percentage difference between the two populations is so large.

The application and exhibits do not show calculation of contractual adjustments to gross revenue by payor source. Instead, Form F.2, Revenue Assumptions, states: "Contractual adjustment is derived from the contractual adjustments experienced in the full calendar year ended 12/31/21 for outpatients treated by proposed physicians. Contractual adjustment averages 64.2%." The KM application has no reasonable basis for the contractual adjustments for the ASC, for several reasons:

- The contractual adjustment for a physician is the difference between the physician's billed charge and the allowed amount for a specific payor. If the billed charge for one physician is higher than another, the percentage contractual adjustment will be higher if the allowed amount is the same. There is no logical reason to assume the difference between the ASC's billed charge and the allowed amount for the ASC would match the average percentage for a group of physicians.

- Generally, the Medicare allowed amount for an ASC is lower than the allowed amount for the average commercial payor. If Medicare covers 50% of ASC patients instead of 29.5%, the contractual adjustment will be higher than assumed, and the net revenue will be correspondingly lower. KM will have materially overstated its net revenue.
- The revenue assumptions state the deductions are based on "outpatients treated by proposed physicians." The language is ambiguous as to whether KM included all outpatient services (including services provided in physician offices) or only services provided in an ASC. It would be unreasonable to base deductions from ASC gross revenue on all physician services to outpatients.

Without reasonable and adequately supported assumptions on payor mix and on the percentage of deductions from gross revenue, the Applicant cannot demonstrate its project is financially feasible.

KM's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). As projected revenues and expenses are based on projected utilization, KM's projected revenues and expenses are also questionable, rendering the KM application non-conforming to Criterion (5). See Criterion (3) discussion above.

The KM application is non-conforming with Criterion (5) for at least these reasons:

- KM fails to properly demonstrate the availability of funds.
- KM understates medical supply expenses.
- KM overstates revenue due to unreasonable assumptions about payor mix and contractual adjustments.
- KM fails to disclose any data to adequately support its assumptions on payor mix and contractual adjustments.
- Because of the understatement of expenses and overstatement of revenues, the project fails to document it is financially feasible by the third year of operations.

The deficiencies addressed under Criterion (7) impact KM's conformity with Criterion (5) and are incorporated by reference here. As explained, KM projects insufficient staff and thus understates operating expenses. Financial feasibility demonstrations must be premised on reasonable cost assumptions. The understatement of costs for staffing results in a lack of reasonable assumptions supporting KM's financial projections.

For the reasons stated above and for any other reasons the Agency may discern, the KM Surgery Center application is non-conforming with Criterion (5).

CRITERION (6)

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

KM's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). Those comments are incorporated here by reference. Because the KM utilization is questionable, KM does not adequately demonstrate that its facility as proposed is needed. Therefore, KM does not demonstrate its conformity with Criterion (6).

The applicant has not considered the capacity at Triangle Surgery Center, a multi-specialty ASC adjacent to the proposed KM. In 2019, Triangle Surgery Center applied and was subsequently CON approved to add OR capacity and to convert from a single-specialty orthopedic ASC to a multi-specialty center, adding pain management, general surgery, and plastic surgery. In the same year, the Agency confirmed TOSC could add two new PRs without a CON. See Exhibit I. Triangle Surgery Center's third OR was not yet operational during FY 2021, and the ASC was operating as multi-specialty at that time. Therefore, there is no publicly available data on the utilization in the third OR, or the volume of additional specialties added to the ASC. The Agency does not yet have data to evaluate how well utilized the additional PRs are, and what non-orthopedic volume Triangle Surgery Center is providing. Having a new ASC adjacent to an existing ASC that just expanded its capacity (with both one OR and two PRs) and the array of services it can provide is a duplication of services. Regarding non-urology procedures, the KM surgery center would unnecessarily duplicate Triangle Surgery Center's services.

KM does not adequately demonstrate that its proposal would not result in an unnecessary duplication of existing or approved services in the service area because KM does not adequately demonstrate that its proposed OR is needed in the service area. See the discussion regarding need and projected utilization found in Criterion (3) which is incorporated herein by reference.

For this reason and others the Agency may discern, the KM application is non-conforming with Criterion (6).

CRITERION (7)

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

KM fails to provide evidence of the availability of resources for all the health manpower and management personnel needed for its proposed center. The CON application form at Section F (Criterion 5), Question 4 explains that applicants must "describe the assumptions and methodology used to complete each form in 4.b," and the form states:

> *The description of the assumption and methodology used for each form should be done in Microsoft Word or similar software and should address each line item on that form. Include the description in Section Q, immediately following the completed form to which it relates.*

The KM application refers to an "on-call schedule" for surgeons, registered nurses, and surgical technicians, to support "urgent and emergent kidney stone treatment" at KM (p. 38).[35] In Section H (Criterion 7) on staffing, KM does not explain its "on-call schedule." The KM Staffing Assumptions state: *"Staffing is based on expected volume with minimum staffing requirements."*

A separate table is labeled "On Call Pay," but no narrative assumptions are included on this page or elsewhere in the application. Here, the project analyst is left to decipher an unsupported "On Call Pay" table with no narrative description of the associated assumptions.

Form H Staffing

On Call Pay	Hourly Rate	Call Rate per HR	Hourly Rate + Call Rate	1st Full Year	2nd Full Year	3rd Full Year
Certified OR/Surgical Technician	$30.00	$4.00	$34.00	$12,410	$18,615	$24,820
Registered Nurse (OR/PR)	$43.00	$5.00	$48.00	$17,520	$26,280	$35,040
Registered Nurse (Pre-op/PACU)	$38.00	$5.00	$43.00	$15,695	$23,543	$31,390
Total				**$45,625**	**$68,438**	**$91,250**
			Expected % of Annual Call Time	20%	30%	40%
			# of Days Open	365	365	365
			Expected # of Call Hours	5	5	5

The "On Call Pay" table provides the following expected pay for after-hours work, beyond salary, using the Certified OR/Surgical Technician – 1st Full Year as an example:

> Salary: 260 days x 8 hrs. per day = 2,080 hrs. = $58,240 ($28/hr.)
>
> On-Call Pay: 365 days x 5 hrs. per day = 1,825 hrs. x 20% = 365 hrs. = $12,410 ($34/hr.)

The applicant's projections equate to 73 days of 5 hours per day (365 hrs.) in Year 1, 109.5 days of 5 hours per day (547.5 hrs.) in Year 2, and 146 days of 5 hours per day (730 hrs.) in Year 3. By

[35] Of course, surgeons will not be on staff at KM. While surgeons indicate they "support the goal" of on-call urology surgical services for patients with urgent urologic needs, none of the physicians commit to being on-call or accepting any specific on-call schedule.

Year 3, KM proposes to perform after-hour surgeries more than 2 days per week, every week of the year.

KM does not explain how its nursing staff will be expected to work an extra 5 hours on potentially one or two or more days every week year-round, with no other personnel onsite. Patients coming in for after-hour surgery will need to check in and check out. Yet, there is no provision for administrators or business office specialists (i.e., "front desk" personnel) to be present onsite to provide after-hours services such as patient check-in and check-out. Per the job description in Exhibit H.3, the Business Office Specialist handles patient admission and reviews all information with the patient, including completing required forms and ensuring HIPAA compliance.

It is unclear how after-hours surgeries can be performed with no support from instrument/sterile processing technicians, materials technicians, or a Director of Nursing (DON). According to the job descriptions in Exhibit H.3, the Instrument/Sterile Processing Technician provides "properly cleaned, sterilized, highly disinfected instruments and supplies." The role of the technician is to maintain a "sanitary environment for the provision of patient care." As detailed in the job description, the technician performs numerous tasks essential to safety and quality in the delivery of surgical services. The Materials Technician performs a variety of functions, including implementing safety measures and practicing universal precautions and infection control measures. A DON has the job of ensuring "high quality, patient-centered care through oversight of the overall function and staffing of the clinical departments."

KM has not documented it has anesthesia coverage for the unscheduled 24/7 surgeries. When an anesthesia group agrees to provide coverage for an ASC, it reasonably expects the coverage is on weekdays, about eight hours per day. The letter from ECAA Anesthesia Specialists (ECAA) in Exhibit I.1 does not state that ECAA will provide on-call after-hours anesthesia. Absent explicit language in a letter or contract, it is unreasonable to assume an anesthesia group has agreed to provide anesthesia on-call, 24/7, with no payment for on-call time.

Performing surgeries with a "skeleton crew" is a questionable plan. Patients expect an understanding of financial obligations and insurance coverage before a surgery, but it appears no personnel will be onsite to complete forms and answer questions. Nothing in the KM application explains how a situation such as a dropped instrument will be handled, with no material tech or instrument tech onsite and no option to access DON support. A proposal to provide 73 days of after-hours surgeries (Year 1) with no instrument/sterile processing tech, no check-in/check-out staff, and no support from a DON or materials technician is highly suspect.

In the chart below, KM indicates "facility staff" will provide equipment maintenance. Yet, in the Form F.3 Expense Assumptions, KM states that equipment maintenance services will be "under contract with outside vendors." The applicant has not clearly demonstrated how it "will make available or make arrangements for" equipment maintenance. Equipment maintenance for a

13,900-square-foot multi-specialty ASC is a significant topic, and it appears the applicant failed to clearly define how it will be addressed.

Except for Housekeeping/Linen, which will be provided through a "local contract," the application states all required services will be "provided by facility staff." The only budgeted personnel for these responsibilities are the Center Administrator, three Business Office Specialists, and presumably some time from the Director of Nursing. At most, this is five FTEs. The number of staff and position titles do not appear adequate to satisfactorily provide sufficient manpower for the project. There are no budgeted professional fees that could cover these responsibilities.

It is customary for an applicant to give details for non-salary operating costs used to provide support services. The support services not accounted for in the KM expense budget include marketing, IT, licensing and certification expenses, accounting, billing software, and recruiting expenses.

X	Administration / Management	Necessary for assuring the responsibilities are fulfilled. This service will be provided through facility staff.
X	Billing / Finance Office / Insurance Claims Filing	Necessary for the charging and reimbursing for the service. This service will be provided through facility staff.
X	Marketing	Necessary for patient referrals to the service. This service will be provided through facility staff.
X	Human Resources / Staff Recruitment and Retention	Necessary for staffing the service. This service will be provided through facility staff.
X	Staff Training / Continuing Education	Necessary for providing training staff. This service will be provided through facility staff.
X	Information Technology	Necessary for providing clinical and administrative services. This service will be provided through facility staff.
	Building Maintenance / Grounds Keeping	Not necessary because the service will not require these services.
X	Equipment Maintenance	Necessary for the continued operation of facility equipment. This service will be provided through facility staff.
X	Purchasing / Materials Management / Central Sterile Supply	Necessary for providing medical and non-medical supplies. This service will be provided through facility staff.
	Dietary	Not necessary because the service will not require these services.
X	Housekeeping / Linen	Necessary for providing clean facilities. This service will be provided through a local contract.
X	Medical Records	Necessary to record the provision of service. Provided by facility staff.
	Social Services	Not necessary because the service will not require these services.
X	Discharge Planning	Necessary to coordinate continuum of care for patients. Provided by facility staff.

For these reasons and any others the Agency may discern, the KM application is non-conforming with Criterion (7).

CRITERION (8)

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

KM does not make the demonstrations required to satisfy Criterion 8. KM provides inadequate information within its application. The comments under Criterion (7) are repeated here by reference.

For these and any other reasons the Agency may discern, the KM application is non-conforming with Criterion (8).

CRITERION (12)

(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.

To demonstrate conformity with Criterion (12), the burden rests with the applicant to demonstrate that the cost and design of its proposed project represent “the most reasonable” alternative and will not unduly increase the costs of providing the service. KM fails to carry its burden.

KM is not conforming to Criterion (12) because it does not adequately demonstrate that the population proposed to be served has a need for the new construction as proposed. See the 2019 Mecklenburg Acute Care Bed and OR Review, which found Atrium Lake Norman non-conforming to Criterion (12).

For these and others reasons the Agency may discern, the KM application is not conforming with Criterion (12).

CRITERION (18a)

(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.**

The KM application does not demonstrate conformity with Policy GEN-3 and Criterion (1). See discussion above, incorporated here. KM did not adequately demonstrate how its proposal will promote the cost effectiveness of the proposed services because KM's projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

KM does not adequately demonstrate how its proposal will promote the cost-effectiveness of the proposed services because KM does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. KM does not adequately demonstrate that its proposal is cost-effective. The discussion regarding availability of funds and financial feasibility found in Criterion (5) is incorporated herein by reference. Consequently, KM does not adequately demonstrate that any enhanced competition would have a positive impact on the cost-effectiveness of the proposed PET service, and it has failed to demonstrate conformity with Criterion (18).

For these and other reasons the Agency may discern, the KM application is non-conforming with Criterion (18a).

PERFORMANCE STANDARDS: 10A N.C.A.C. 14C.2103

(a) An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.

(b) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

KM does not adequately demonstrate the need for the proposed project, or that the projected utilization is reasonable and adequately supported.

Fundamental issues exist with KM's utilization projections. As explained above, KM fails to explain how it will provide after-hours surgeries with no administrative staff or sterile tech support. The KM "model" is based on addressing emergency kidney stone cases. Because the need and plans for rendering this care are unreasonable and inadequately supported, the associated utilization projections are called into question.

KM uses highly questionable assumptions under which a wide array of surgeons (including numerous urologists, plus an array of other surgical specialists) will each perform a *very small* number of weekly surgeries at KM. While this may be an attempt to present "conservative" projections, the result is an unreasonable forecasted utilization. Surgeons note an "interest" in being credentialed to perform cases at KM, but none indicate a plan to perform limited weekly cases at KM. It is unreasonable to believe numerous surgeons will each use an ASC to perform only one to three surgeries each week. The utilization at KM will assuredly ***not*** be as KM has described in its application. The burden was on KM to project a reasonable plan to "fill" its ASC. KM's plan is unreasonable, and the analyst cannot write a new utilization plan for KM or substitute different projections or assumptions in place of those provided in the application.

The full discussion regarding analysis of need and projected utilization is found in Criterion (3) and incorporated here by reference.

Because KM does not demonstrate the need for the proposed project or that the projected utilization is reasonable and adequately supported, the applicant cannot demonstrate the need for the one new OR based on the OR Need Methodology in the 2022 SMFP. Therefore, the application is not conforming with this Rule.

COMMENTS SPECIFIC TO DUKE GREEN LEVEL ASC

CRITERION (1)

(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.

Policy GEN-3: Basic Principles

"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."

Although the Duke Health proposal to relabel two PRs as ORs would not involve the approval of more than the two ORs shown as needed in the 2022 SMFP Need Determination, it is inconsistent with Policy GEN-3 and, therefore, does not conform to Criterion (1). The Duke Health project fails to effectively address the 2022 SMFP Need Determination because it will not result in a net increase of surgical capacity and will not bring Wake County residents any "new" surgical capacity.

CRITERION (3)

(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.

Duke Health is approved to develop a new ASC with one OR and five PRs, per Project ID # J-11557-18. In its current application, at a cost of $1.5 million, it asks for CON approval to relabel two PRs as ORs, resulting in an ASC with three ORs and three PRs.

Relabeling two approved PRs as ORs serves no practical purpose and is unnecessary for Duke Health to perform and fulfill the representations in its application. The relabeling serves no public purpose, as it does not benefit consumers or Duke Health. The Agency cannot approve the Duke Health application because Duke Health is not proposing an activity that requires OR CON approval.

Unlike Oakview, Duke Health can perform and fulfill its representations without an OR CON approval:

- A CON is only required for a "new institutional health service" (NIHS), as defined in the CON Law.[36]
- An approved ASC can develop and increase surgical services without OR CON approvals because the CON Law does not define a provider's development or increase in surgical services as an NIHS.
- An approved ASC can add or renovate physical spaces to offer more surgical care by adding PRs without OR CON approvals because the development, establishment, increase in the number or relocation of PRs is not as an NIHS.
- Duke Health can perform and fulfill its application representations by establishing and expanding surgical offerings by performing surgical procedures in its approved PRs *without approval of its OR CON application*.

The Agency has repeatedly confirmed that adding a PR in a licensed facility does not require a CON:

- In 2012, the Agency confirmed that PRs in licensed ASCs and hospitals are only regulated to the extent of ensuring compliance with Life Safety Code provisions; using or establishing a PR does not require "any determination from the [CON] Section." See Exhibit G.
- In response to a 2017 inquiry by North Carolina Specialty Hospital (NCSH), the Agency confirmed NCSH could develop an additional PR without a CON. *See Exhibit* H.
- In response to a 2019 inquiry from Triangle Orthopaedic Surgery Center (TOSC), the Agency confirmed TOSC could add two new PRs without a CON. See Exhibit I.

[36] N.C. Gen. Stat. § 131E-176, -178.

- The Agency's Hospital LRA form acknowledges that hospitals can provide surgical services in PRs "which are not licensed as operating rooms … but are used for performance of surgical procedures." See 2022 Hospital LRA, Sections F.9.c. and F.9.f., attached as Exhibit J.

Agency witnesses, including Senior Project Analyst Michael McKillip, have testified on the Agency's position that PRs can be added *without a CON*. (Such testimony was elicited by counsel for WakeMed.) See Excerpts of the June 2020 deposition of Mr. McKillip, attached as Exhibit K.

> *… development of procedure rooms are not considered a new institutional health service under the statute. So applicants, in my experience, can develop them without a Certificate of Need through – just by obtaining an exemption letter.*
>
> (Michael McKillip, Vol. 2, p. 265).

Mr. McKillip also testified the Agency does not limit how PRs are constructed, equipped, or staffed. (*Id.*) In short, PRs can be constructed, equipped, and staffed identically to ORs, and any surgery procedure that can be done in an OR can be done in a PR. (*Id.* at p. 275.)

A PR can be functionally equivalent to an OR. The number of facilities that provide surgical services with a combination of OR and PR capacity shows North Carolina providers can and do use PRs in the same fashion as ORs. As shown on its 2022 LRA, Duke Health performs surgeries in both its ORs and PRs lawfully and appropriately. Duke Raleigh Hospital performed 5,815 cases in six procedure rooms FY 2021.[37]

Existing providers of surgical services are in an enviable position. Under current law, hospitals and ASCs can expand surgical capacity without new OR CON approvals by adding PRs to their existing or approved facilities or to a proposed hospital or ASC. A provider with multiple ORs in a county can relocate one or more of its ORs to develop a new ASC or hospital without CON approval for additional ORs. A provider can designate vacated ORs as PRs and continue to provide the same surgical services as before.

The only applicant who needs CON approval of a new OR is an ASC applicant with no existing ORs in a county. Only new market entrants face a true barrier to entry under current CON Law. Oakview's ophthalmic ASC will be an option for patients in the area only if the Agency approves its OR CON application. For Oakview, unlike Duke Health, the OR CON is an essential legal requirement.

Duke Health's application required it to certify its intent to carry out its project as proposed. Thus, one must assume Duke Health's project is intended for its stated purpose, not to prevent the development of competing ORs or to "stockpile" ORs that can later be deployed to develop new ASC locations in the service area. Under North Carolina CON Law and the corresponding

[37] Duke Raleigh Hospital 2022 LRA, pp. 12–13.9(f).

licensure statutes, Duke Health can implement its proposed project *without the OR CON approvals it requests.* Because Duke Health can perform and fulfill its representations without OR CON approvals, the Agency has no authority or legal basis to grant Duke Health's application for additional ORs.

Despite its large and growing population, determinations of need for new ORs in Wake County have been infrequent, with few or none in many SMFPs. Awarding an OR CON to an applicant that does not need one for its project would squander the opportunity to add needed OR capacity for Wake County residents.

The award of an OR CON to Duke Health would only serve to "place a different label" on rooms which, with some unregulated renovations, Duke Health can already use to perform surgical services. Patients in Wake County who need surgical services will be no better served by Duke Health, whether the spaces are labeled "OR" or "PR."

Oakview, however, cannot develop its proposed ASC without CON approval of one OR. If the Agency unnecessarily approves the OR application of Duke Health or other applicants who do not need an OR CON, this limits the approvals available to Oakview. Approving the Duke Health OR application could reduce competition from a new provider in Wake County.

Duke Health cannot claim it is unable to offer and/or expand its surgical services without a new OR CON approval. Duke Health has the lawful ability, *without a new OR CON*, to:

- Develop or establish PRs (by renovation or new construction) built, equipped, and staffed in a fashion identical to their existing or approved ORs in Wake County;
- Perform surgical procedures in PRs in a manner designed to ensure the delivery of safe, high-quality surgical services.

Nothing justifies the award of an OR CON to Duke Health when nothing in its application establishes that such CON approvals are necessary for it to perform or fulfill its stated intentions to expand surgical capacity in Wake County. Specifically, in its application as filed, Duke Health:

- Cites no law or regulation (whether North Carolina or federal) which requires certain types of surgical cases to be performed in an OR instead of a PR;
- Does not represent that any payor (government or commercial) has imposed a requirement for reimbursement that would dictate that certain surgical cases be performed in an OR instead of a PR;
- Cites nothing indicating that an OR "label" is needed to secure more dollars in reimbursement than would otherwise be received for the same surgical services absent the OR "label;"

- Does not argue that an OR CON is needed to build a room of a desired size or with any certain equipment or to employ any specialized staff;
- Identifies no "standard of care" or clinical or operational standard or expectation governing their facilities or their medical staffs that would require certain cases to be performed in an OR instead of a PR.

If Duke Health sought to justify approval of its OR application based on any law, regulation, or authority that would require an OR CON, the burden was on Duke Health to explain that basis in its application. The Duke Health application, as filed, cannot now be amended to include citation to any of the above, as the deadline for the submission of application materials has now passed.

Reasonable and adequately supported utilization projections must show need for a proposed project. If the projected utilization is not reasonable and adequately supported, the application cannot be approved.

In this review, Duke Health seeks to develop two ORs "in lieu" of two PRs at Duke Green Level ASC. Duke Health first applied to develop Duke Green Level ASC in 2018, seeking four of the six ORs identified per the 2018 Need Determination. It was denied.

When Duke Health first proposed the development of Duke Green Level ASC in 2018, the Agency concluded the information Duke Health provided was not reasonable and did not adequately support a determination that the proposal would maximize healthcare value, because its projected utilization was not based on reasonable and adequately supported assumptions.

The Agency found Duke Health's projected surgical case volumes and growth rates questionable because Duke Health reported in its 2019 Hospital LRA that historical surgical case volume data for Duke Raleigh Hospital had been overstated for an unknown number of years. The 2019 Hospital LRA was emailed to Martha Frisone, Chief, on January 23, 2019, with this statement:

> *While total surgical cases continue to increase, in previous years, Duke Raleigh inadvertently included all cases performed in the surgical suite, including procedures in both licensed ORs and in procedure rooms, in this category. … We apologize for our previous reporting errors and greatly regret any difficulties that this causes in the planning process or the review of Wake County certificate of need applications.*

The Agency findings depicted "the extent of the overstatement for FY 2018" in the Duke Raleigh Hospital inpatient, outpatient, and total surgical case volumes. At that time, the Agency questioned the propriety of Duke Health using a total "surgical case" count that included both OR and PR volumes. Nonetheless, Duke Health has and continues to "count" both OR and PR volumes when evaluating its historical utilization and defining the growth in its surgical case volumes. Based on its filings, Duke Health believes it is appropriate to include both OR and PR cases when evaluating

its utilization and growth, the extent of surgical demand, and ultimately, the need for surgical capacity at Duke Health facilities.

Duke Health cannot have it both ways. If Duke Health wants to evaluate utilization and demand and forecast its needs based on the volume of cases performed in both its ORs and PRs, it is acknowledging there is no functional difference between the volumes of surgical cases served in its ORs and PRs. If that is true, as Duke Health states in multiple CON applications, then its current application to relabel PRs as ORs is, at best, a logical inconsistency, and a waste of its resources.

In 2018, the Agency questioned Duke Health's assumptions about the extent of cases that would "shift" to its Green Level ASC in west Cary from Duke Raleigh Hospital in Raleigh. The Agency termed Duke Health's assumptions "**questionable**." While the Agency denied the project for four ORs and three PRs, Duke Health secured a CON for its proposed ASC with one OR and five PRs in a settlement that followed a challenge filed at the Office of Administrative Hearings.

For that very project, Duke Health is now seeking CON approval for two ORs "in lieu" of two PRs. Yet, the accuracy and reasonableness of Duke Health's data and projections remain an issue, as the table below shows:

- In its 2018 CON application, Duke Health told the Agency it performed **12,604** outpatient (OP) surgical cases in FY 2018 at Duke Raleigh.
- Duke Health reported an **8.4%** compound annual growth rate (CAGR) (FY14–18) for OP cases at Duke Raleigh, repeatedly terming it a "strong outpatient surgery growth rate."
- In this application, Duke Health states it performed only **11,349** outpatient surgical cases in FY 2018 at Duke Raleigh.
- Duke Health now identifies a **3.6%** CAGR (FY18–22) for OP cases at Duke Raleigh.

Historical numbers reported by Duke Health vary from CON application to CON application.

Discrepancies in Total Outpatient Surgical Cases at Duke Raleigh, as Reported in Duke CON Applications

	FY2015	**FY2016**	**FY2017**	**FY2018**
Per Duke's 2018 Application (p. 120) (Project ID # J-11557-18)	9,875	10,855	11,084	12,604
Per Duke's 2022 Application (p. 132) (Project ID# J-012261-22)	9,464	9,895	10,460	11,349

Not only have Duke Health's historical numbers changed, its "reasonable" assumptions for growth differ materially from application to application. For instance, when it applied in 2018, Duke Health thought it would have many more cases at Duke Raleigh than it forecasts in the current application. In its 2018 application, Duke Health forecasted its "available" OP cases at Duke Raleigh would be over 20,000 and over 21,000 in FY 2023 and 2024, respectively. Yet, in this application, Duke Health projects its "available" OP cases at Duke Raleigh will be under 17,000 in each of FY 2023 and 2024.

When Duke Health applied for its Green Level ASC in Wake County in 2018, Duke had only Duke Raleigh Hospital and no ASCs. Since then, Duke Health has been approved for a new hospital in Wake County, Duke Green Level Hospital (Project ID # J-12029-21), and has been approved via settlement for Duke Green Level ASC. Duke Health also now has Duke Health Raleigh ASC (Project ID # J-12212-22), Duke Health Arringdon ASC (Project ID # J-12075-21), and Duke Health Garner (Project ID # J-11966-20). In each of its respective applications and settlements, Duke Health projected that Duke Raleigh Hospital would "shift" cases to Arringdon ASC, Duke Health Garner ASC, Duke Health Raleigh ASC, Duke Health Green Level Hospital, and Duke Green Level ASC.

In 2018, after shifts to Arringdon ASC and Green Level ASC, Duke Health suggested its remaining OP cases in FY 2024 at Duke Raleigh would total 12,392.

Yet, remarkably, even though it significantly lowered its "available" OP case volume projections for Duke Raleigh and now projects to shift volume to *multiple* facilities, in this application, Duke Health still asserts that the remaining OP cases in FY 2024 at Duke Raleigh will total 11,402.

Something does not add up. In 2018, Duke Health started with a more robust volume of OP cases, grew it by a more aggressive growth assumption, and indicated shifts to only two area facilities, Arringdon and Green Level. It ended with a projection of about 12,000 OP cases at Duke Raleigh in FY 2024.

Now, Duke Health corrects its starting OP volume for FY 2024 to a lower figure, uses a lower growth assumption, and plans for shifts to more facilities, yet it still ends up with a projection of about 11,000 OP cases at Duke Raleigh in FY 2024.

If its current application is approved, Duke Green Level ASC will have three ORs and three PRs. According to the floor plan, the rooms look comparable, if not identical, in size. The application does not indicate that the ORs will be built or equipped any differently than the PRs.

Yet, significantly, Duke Health projects a much higher utilization in the rooms it has labeled as ORs and, correspondingly, a much lower utilization in its PRs. Instead of making an operationally reasonable assumption that all surgical rooms at its ASC will be scheduled to accommodate patient demand, and thus all "filled" with surgical cases at about the same levels, Duke Health made a

different assumption. In its partial year 2026 and across its first three full years, Duke Health assumes:

	Partial Yr 2026	2027	2028	2029
OR Cases	812	1,532	2,374	3,279
PR Cases	344	687	1,007	1,517

In other words, Duke Health will have a six-room ASC but projects it will schedule about twice as many cases in its three ORs than in its three PRs, although the rooms may be identical in size and equipment.

While there is no reason for Duke Health to assign longer-duration cases to rooms labeled ORs if all rooms are functionally equivalent, assigning more "complex" orthopedic or other cases to the ORs with so-called minor surgical cases done in the PRs would result in fewer cases in the ORs than in the PRs, not the other way around.

By its projections, Duke is assuming 1,000+ cases per OR but only about 500+ cases per PR. If its ORs will be used for hip, knee, or shoulder surgeries that last well over an hour and its PRs will be used for short-duration general surgery cases (e.g., removing a mole), it is simply not credible that the ORs will accommodate 1,000+ annual cases per room but the PRs will run only 500+ cases per room over the same year. This unsubstantiated assumption may be an exercise in increasing OR hours to meet the performance standard. Duke Health provides nothing to substantiate its arbitrary assignment of over twice the volume of cases to its three ORs (3,279 in Year 3) as compared to its three PRs (1,517 in Year 3).

Both need and financial feasibility must be based on reasonable assumptions, and there appears to be nothing reasonable about assigning over two-thirds of Year 3 cases to three ORs and only one-third of cases to three PRs. Nothing in the application explains why it would be reasonable to assign two-thirds of surgical cases to three rooms and one-third of surgical cases to the other three rooms, considering all six rooms are equivalent in size and equipment.

If Duke Health's forecasted surgical case volumes were scheduled to use all six rooms equally, Duke Health's projected volume per OR would drop precipitously.

Duke Health's financial projections are also tied to its unsubstantiated distinction between OR and PR cases. Duke Health assumes the average gross charge for cases in the ORs will be roughly ten times the average gross charge for cases in the PRs. In Year 3, Duke Health assumes an OR case will have an average gross charge of $12,501 but a PR case will have an average gross charge of only $2,749.

This higher gross charge could indicate Duke Health is assuming longer-duration, more complex cases for its ORs. If so, it is counter-intuitive that the three ORs will be much more highly utilized compared to the PRs, considering that all six rooms are available during the same hours each week.

Only about 34% of Duke Health's projected cases will be orthopedic cases (1,140 in Year 3) (Duke Health app., p. 142). About 43% of its cases will be a combination of general and ophthalmic cases (1,403 in Year 3). (*Id*.) The breakout of cases by specialty does nothing to support the assumption that two-thirds of Duke Health's cases will have an average gross charge of $12,500+ and only one-third will have a much lower $2,700+ average gross charge (Duke Health app., p. 157). Both the need and financial projections for Duke Health are based on an unsupported assumption about the split of utilization between its ORs and PRs.

For all the reasons noted above and for reasons the Agency may discern, Duke Health does not show conformity with Criteria (3) and (5) and should be found non-conforming to Criteria (4), (6), and (18a) for the same reasons.

CRITERION (4)

(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.**

Duke Health has not adequately demonstrated that the alternative proposed in its application is the most effective alternative to meet the need because:

- Duke Health does not demonstrate the need for its proposed project, or that the projected utilization is reasonable and adequately supported. See the discussions about need and projected utilization under Criterion (3) above. A project that does not provide reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- Duke Health does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. See the discussion on financial feasibility under Criterion (5) below. Duke Health does not demonstrate that developing the project is financially feasible, and thus cannot demonstrate that the proposed alternative is the most effective alternative to meet the need.
- Duke Health does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. See the discussion about unnecessary duplication under Criterion (6) below. An unnecessarily duplicative project cannot be the most effective alternative to meet the need.

- Duke Health does not provide credible information to explain why it believes its proposed project is the most effective alternative.
- The most effective alternative for Duke Health, given its stated objectives, is not to relabel two PRs as ORs and to avoid the expense of the CON process.
- Duke Health did not adequately demonstrate that filing this application is the most effective alternative to meet its needs, because relabeling the PRs serves no practical healthcare purpose.
- Duke Health's proposal to relabel two PRs as two ORs is not the most effective alternative because it will not meet any unaddressed need, nor will it benefit an underserved population. It only wastes resources for an unnecessary CON application. See further discussion below.
- Duke Health is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Duke Health notes on page 144 of its application, "Procedure rooms are not regulated by CON." Duke Health knows Duke Raleigh Hospital already has PRs equipped to accommodate surgical cases, and it acknowledges that its PRs are better outfitted and sized than some of its ORs:

> *The [PRs] located in [Duke Raleigh Hospital's] surgical suite are larger and more equipped than some of [its other] licensed ORs and are built to safely accommodate a range of surgical procedures.*
>
> (Duke Health application, p. 38)

Duke Health can similarly equip its five approved PRs for surgical procedures. It has no need to designate rooms as PRs "in lieu of" ORs to develop and equip these rooms to "safely accommodate a range of surgical procedures."

The Duke Health floor plan shows the PRs to be relabeled as ORs will be identical in size to the rooms now labeled as ORs. (Exhibit K.2 is labeled "Green Level Medical Campus FSED" but presumably shows Duke Health's approved surgery center that is the subject of its application.)

Agency approval of the Duke Health project would award both ORs in the 2022 SMFP but not expand surgical capacity or improve geographic access to surgical services in Wake County. Approval would not introduce a new provider to the service area. The Duke Health project does not benefit the public and does not represent the best use of scarce OR assets.

The only benefit to Duke Health from approval of its application is to deny approval of applications that might compete with Duke Health. Therefore, the proposal is not an effective alternative for Wake County residents.

For these reasons and such others as the Agency may discern, the Duke Health application is not conforming with Criterion (4).

CRITERION (5)

(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.

Per Criterion (5), the financial feasibility of a proposed project must be based on "reasonable" projections of costs. Accordingly, the Agency expects cost projections to be based on "reasonable and adequately supported assumptions."

As explained in the above discussion of non-conformity with Criterion (3), both need and financial showings for Duke Health are based on an unsupported assumption about the split of utilization between its ORs and PRs. While not repeated here, the above discussion is incorporated by reference as to Criterion (5).

As regards adding $200,000 in new construction costs, Duke Health's architect letter is incomprehensible. It states the entire floor will be built out before the "conversion" of the two rooms to ORs:

> *with the assumption of some supporting space (i.e., sterile core growth, adjacent corridors, additional prep/PACU bays built, etc.).*

There is no line drawing in the Duke Health application that shows any additional bays or new sterile core space or corridors. There is nothing to indicate that any such drawings exist. Inasmuch as the rooms in question are in the middle of an approved ASC, it is difficult to understand where new bays and sterile core space and corridors would be included. If new pre/PACU bays, sterile core spaces, and corridors are being built, is only $200,000 is a reasonable cost assumption?

The architect instead seems to attempt to validate the estimate at $200,000 because the space to be occupied by the two rooms represents 33% of the total ASC square footage. The architect identifies the cost to build the approved project, suggesting that the two ORs to be built in lieu of two PRs, represent "33% of the overall 3-OR/3-[PR] setup." In other words, the architect states the two rooms will "build-out" 7,000 square feet of the overall 21,000 square feet.

On first blush, this calculation is off. Two rooms, standing alone, do not represent 7,000 square feet. The calculation appears to be simplistic division: 21,000 square feet divided by 6 total rooms

= 3,500 square feet per room, such that 2 rooms are associated with 7,000 square feet. If taken at face value and the two rooms (perhaps with associated spaces?) represent 33% (or 7,000 of the overall 21,00 square feet), the estimate of $200,000 in construction build-out costs is wildly out of line. The total ASC project cost is over $21 million dollars. If 33% of the cost is to be associated with these two rooms, that would be approximately $7 million dollars, not $200,000. Assuming the expenditure for the rooms was already approved in the first application, the question then is: Why should Duke Health spend hundreds of thousands in additional costs to relabel those rooms? The estimate of $200,000 is not 33% of the total cost, nor is it 33% of any other figure. The 33% calculation in the architect letter offers no valid explanation or substantiation of the $200,000 figure in the Duke Health application.

The architect states that "total project costs for incremental equipment and other work related to this project changes [are] $885,000." This appears to be a total derived from a $660,000 increase for medical equipment + $100,000 in non-medical equipment + $25,000 more for furniture. The other $100,000 is perhaps for additional architect/engineering and consultant fees.

Nowhere in the architect letter or in the capital cost worksheet assumptions does Duke Health specify what is meant by "incremental equipment and other work," nor does it provide anything to justify the reasonableness of the associated costs.

Why would labeling rooms as ORs instead of PRs require $885,000 of new "equipment and other work," and what is the "need" justification for such expenditures? Specifically, why would labeling rooms as ORs instead of PRs require $660,000 in additional medical equipment or $125,000 more in non-medical equipment and furniture?

Duke Health refers generally to its experience; however, the application provides no list of the equipment Duke Health is buying and at what per-item cost. The architect offers no opinion on the reasonableness of the equipment costs.

Among other significant and obvious issues with the Duke Health application, the application does not explain or provide consistent information on the construction/renovation plans for its project, nor does Duke Health provide any description or list supporting its plans to acquire over a half-million dollars in new medical equipment. Criterion (5) requires financial showings to be supported by reasonable cost assumptions. With no explanation or detail, the Duke Health application fails to provide sufficient assumptions to support the construction and equipment cost projections associated with developing two ORs "in lieu" of two PRs.

Duke Green Level ASC does not appear to include any administrative staffing in its Form H. Additionally, the full costs required for supporting the proposed Duke Green Level ASC are not likely captured by the "corporate allocation" line. These are estimated at 1% of gross charges, or $225,969 in the project's first full year of operations. This amount is supposed to cover all administrative expenses not included on Form H (e.g., IT, billing, administration, etc.). Duke

Green Level ASC does not provide narrative support for its assumption that all these costs are captured in the corporate allocation line.

Additionally, Duke Green Level ASC failed to submit a Form F.2b for its PRs. Instead, it submitted Forms F.2b for the total facility and ORs. Presumably, the PRs account for the difference between the two. If that is the case, the PRs show a loss of over $2 million dollars in Year 3 ($2,269,043 total facility net income *minus* $4,373,271 OR net income *equals* -$2,104,228). Duke Green Level ASC provides no explanation for this loss and therefore does not provide adequate support for the financial feasibility projected in Form F.2b.

For these reasons and others the Agency may discern, Duke Health does not demonstrate its conformity with Criterion (5).

CRITERION (6)

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

Duke Health's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). Those comments are incorporated here by reference. Because the Duke Health utilization is questionable, Duke Health does not adequately demonstrate that its facility as proposed is needed. Therefore, Duke Health does not demonstrate its conformity with Criterion (6).

Duke Health does not adequately demonstrate that its proposal would not result in an unnecessary duplication of existing or approved services in the service area because Duke Health does not adequately demonstrate that its proposed OR is needed in the service area. The Duke Health application unnecessarily consumes the ORs the Agency is authorized to approve. As it does not need the two ORs for its ASC, approval of those ORs would unnecessarily duplicate the OR already approved for the ASC. See the discussion regarding need and projected utilization found in Criterion (3) which is incorporated herein by reference.

For these reasons and others the Agency may discern, the Duke Health application is non-conforming with Criterion (6).

CRITERION (18A)

(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.

Duke Health projects its percentages of underserved and elderly patients on its experience at other Duke Health facilities (Duke Health app., p. 108). The demographic and socioeconomic makeup of the Cary community differs from Wake County's other communities, with lower poverty levels and higher commercial insurance coverage. Therefore, the applicant is likely overstating its percentages of charity care, Medicaid, and Medicare patients.

Relabeling two approved PRs as ORs will not have a positive impact upon the cost-effectiveness, quality, and access to the services proposed. Approval of this application will have a negative impact on competition by requiring the Agency to deny applications from Oakview and other new providers to Wake County.

For these reasons and such others as the Agency may discern, the Duke Health application is not conforming with Criterion 18a.

PERFORMANCE STANDARDS: 10A N.C.A.C. 14C.2103

(a) An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.
(b) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

Duke Health does not adequately demonstrate the need for the proposed project, or that the projected utilization is reasonable and adequately supported. The full discussion regarding analysis of need and projected utilization is found in Criterion (3) and incorporated here by reference.

Because Duke Health does not demonstrate the need for the proposed project or that the projected utilization is reasonable and adequately supported, the applicant cannot demonstrate the need for the one new OR based on the OR Need Methodology in the 2022 SMFP. Therefore, the application is not conforming with this Rule.

COMMENTS SPECIFIC TO WAKEMED GARNER HOSPITAL

CRITERION (1)

(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.

Although the WakeMed proposal to develop two hospital-based ORs is consistent with the 2022 SMFP Need Determination, it is inconsistent with Policy GEN-3. Therefore, it does not conform to Criterion (1).

Policy GEN-3: Basic Principles

"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 WakeMed application does not demonstrate consistency with Policy GEN-3. Therefore, it does not conform to Criterion (1).

The WakeMed proposal does not maximize healthcare value for resources expended. The projected capital cost of the proposal is $214,000,000. The application acknowledges this is a "relatively large capital expense," but fails to demonstrate that such an expenditure is warranted, especially considering potential alternatives for the proposal (WakeMed app., p. 34).

The Garner area will be home to three approved ASCs: Duke Health Garner ASC (1 OR and 2 PRs), Orthopaedic Surgery Center of Garner (1 OR and 2 PRs), and Valleygate Surgery Center (1 OR and 2 PRs). WakeMed cannot demonstrate that adding two ORs near three developing projects maximizes value for resources expended.

WakeMed's projected outpatient origin is based on surgical patients projected to shift from other WakeMed facilities. (WakeMed app. p. 49). WakeMed fails to demonstrate that a significant

expenditure related to developing a new hospital and operating rooms is consistent with maximizing value when the proposal simply shifts patients from one facility to another with little difference in travel times.

WakeMed fails to demonstrate that the proposal maximizes healthcare value for Wake County residents. The "primary service area" excludes a large portion of Wake County yet includes as much or more area of Johnston County in its "primary service area" than Wake County. This proposal does not maximize healthcare value for residents of Wake County as it is intended to serve a large portion of Johnston County, which has no need for additional operating rooms. As stated in the application, "the purpose of the proposed project is to enhance access to care for WakeMed patients who currently travel to WakeMed-affiliated facilities for care." (WakeMed app., p. 60). This does not maximize value for all patients in Wake County and demonstrates an improper emphasis on serving only those individuals who already utilize WakeMed facilities.

Multiple alternatives would be a more effective use of resources, including, at the very least, relocating existing ORs from within the WakeMed system. And, as referenced earlier, the immediate area of the proposed project not only has sufficient OR access, but the proposed "primary service area" is home to UNC Health Johnston which, according to the 2022 SMFP, has two ORs with an estimated surplus of 1.65 ORs.

The WakeMed proposal is not an effective deployment of resources, does not maximize value and cannot be found confirming with Criterion (1).

CRITERION (3)

(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.

WakeMed proposes the development of a new hospital and seeks CON approval for two ORs in that hospital. The development of a hospital requires CON approval because the development of a new health service facility is a NIHS. This hospital results from the transfer of 22 beds from WakeMed Raleigh and 12 ED rooms from WakeMed Garner Healthplex. However, WakeMed proposes new ORs rather than transferring existing assets as it did for the other components of its hospital. WakeMed does not need CON approval for two new ORs for its proposed hospital. The WakeMed system has forty-one (41) licensed ORs in Wake County; the system has a reported surplus of 2.64 ORs per the 2022 State Medical Facilities Plan. WakeMed can transfer two existing ORs to the new hospital and redesignate the vacated ORs as PRs with no change in equipment or

use. Considering WakeMed has a reported surplus of two ORs, the transfer is even easier. The Agency cannot grant WakeMed a CON for two new ORs because WakeMed can implement its proposed project with its existing ORs.

Unlike Oakview, WakeMed can perform and fulfill its representations without approval of an OR CON.

- A CON is only required for a "new institutional health service" ("NIHS") as defined in the CON Law;[38]
- A proposed hospital can develop and offer surgical services without OR CON approvals because the CON Law does not separately define a provider's development of surgical services in a hospital as an NIHS;
- WakeMed can perform and fulfill its application representations by establishing surgical offerings in its proposed hospital by transferring one of its existing system ORs.

WakeMed can also develop PRs at its hospital in which it can perform surgical procedures.

- In 2012, the Agency confirmed that PRs in licensed ASCs and hospitals are only regulated to the extent of ensuring compliance with Life Safety Code provisions and using or establishing a PR does not require "any determination from the [CON] Section." *See* Exhibit G.
- In response to a 2017 inquiry by North Carolina Specialty Hospital ("NCSH"), the Agency confirmed NCSH could develop an additional PR without a CON. *See* Exhibit H.
- In response to a 2019 inquiry from Triangle Orthopaedic Surgery Center ("TOSC"), the Agency confirmed TOSC could add two new PRs without a CON. *See* Exhibit I.
- The Agency's Hospital License Renewal Application form acknowledges that hospitals can provide surgical services in PRs "which are not licensed as operating rooms … but are used for performance of surgical procedures." *See* 2022 Hospital License Renewal Application, Sections F.9.c. and F.9.f., attached as Exhibit J.

Agency witnesses, including Senior Project Analyst Michael McKillip, have testified on the Agency's position that PRs can be added *without a CON*. (Such testimony was elicited by counsel for WakeMed.) See Excerpts of the June 2020 deposition of Mr. McKillip, attached as Exhibit K.

[38] N.C. Gen. Stat. § 131E-176–178.

> *… development of procedure rooms are not considered a new institutional health service under the statute. So applicants, in my experience, can develop them without a Certificate of Need through – just by obtaining an exemption letter.*
>
> (Michael McKillip, Vol. 2, p. 265)

Mr. McKillip also testified that the Agency does not limit how PRs are constructed, equipped, or staffed. (*Id.*) In short, PRs can be constructed, equipped, and staffed identically to ORs and any surgery procedure that can be done in an OR can be done in a PR. (*Id.* at p. 275.)

Assuming it is properly equipped, a PR can be functionally equivalent to an OR. The number of facilities which provide surgical services with a combination of OR and PR capacity show North Carolina providers can and do use PRs in the same fashion as ORs. WakeMed performs surgeries in both its ORs and their PRs lawfully and appropriately.

Existing providers of surgical services are in an enviable position. Under current law, hospitals and ASCs can expand surgical capacity without new OR CON approvals by adding PRs to their existing or approved facilities or to a proposed hospital or ASC. A provider with multiple ORs in a county, such as WakeMed, can relocate one or more of its ORs to develop a new ASC or hospital without CON approval for additional ORs. A provider can designate the vacated ORs as PRs and continue to provide the same surgical services as before.

The only applicant who needs CON approval of a new OR is an ASC applicant with no existing ORs in a county. Only new market entrants face a true barrier-to-entry under current CON Law. Oakview's ophthalmic ASC will be an option for patients in the area only if the Agency approves its OR CON application. For Oakview, unlike WakeMed, the OR CON is an essential legal requirement.

WakeMed's application required it to certify its intent to carry out its project as proposed. Thus, one must assume WakeMed's project is intended for its stated purpose and not to prevent the development of competing ORs nor to "stockpile" ORs that can later be deployed to develop new ASC locations in the service area. Under North Carolina CON Law and the corresponding licensure statutes, WakeMed can implement its proposed hospital project *without the OR CON approvals it requests.* Because WakeMed can perform and fulfill its representations without OR CON approvals, no authority or basis exists for the Agency to grant its application for additional OR CON approvals.

Despite its large and growing population, determinations of need for new ORs in Wake County have been infrequent, with few or none in many SMFPs. Awarding an OR CON to an applicant that does not need one for its project would squander the opportunity to add needed OR capacity for Wake County residents.

WakeMed has 41 approved ORs and a system surplus of more than two. It can meet the OR needs of the proposed hospital by transferring two ORs and relabeling the vacated rooms as PRs with no loss in surgical capacity. Oakview, on the other hand, cannot develop its proposed ASC without CON approval of one OR. If the Agency unnecessarily approves the WakeMed OR application, this limits the Agency cannot approve Oakview. Approving the WakeMed OR application prevents competition from a new provider in Wake County.

WakeMed cannot justifiably claim that it cannot offer and/or expand its surgical services without new and separate OR CON approvals. In its proposed hospital, WakeMed has the lawful ability, *without OR CON approvals*, to:

- Transfer existing ORs to a new facility
- Designate vacated ORs as PRs equipped, and staffed in a fashion identical to their existing ORs in Wake County;
- Perform surgical procedures in PRs in a manner designed to ensure the delivery of safe, quality surgical services.

Nothing justifies the approval of WakeMed's OR CON when it has alternatives that make the CON approval unnecessary for it to perform or fulfill its stated intentions to offer surgical capacity in its proposed new hospital in Wake County while maintaining current surgical capacity at its existing facilities.

Specifically, in its application as filed, WakeMed:

- Cites no law or regulation (whether North Carolina or Federal) which requires certain types of surgical cases to be performed in an OR instead of a PR;
- Does not represent that any payor (government or commercial) has imposed a requirement for reimbursement that would dictate that certain surgical cases be performed in an OR instead of a PR;
- Cites nothing indicating that an OR "label" is needed to secure more dollars in reimbursement than would otherwise be received for the same surgical services absent the OR "label;"
- Does not argue that an OR CON is needed to build a room of a desired size or with any certain equipment or to employ any specialized staff;
- Identifies no "standard of care" or clinical or operational standard or expectation governing their facilities or their medical staffs that would require certain cases to be performed in an OR instead of a PR.

If WakeMed sought to justify approval of its OR application based on any law, regulation, or authority that would require an OR CON, the burden was on WakeMed to explain that basis in its

application. The WakeMed application, as filed, cannot now be amended to include citation to any of the above as the deadline for the submission of application materials has now passed.

Reasonable and adequately supported utilization projections must show need for a proposed project. If projected utilization is not reasonable and adequately supported, the application cannot be approved.

WakeMed's proposal defines its "primary service area" to exclude large portions of Wake County and include significant portions of Johnston County. Per the 2022 SMFP, Johnston County has no additional need for OR services. The population WakeMed proposes to serve has no need for the services proposed. WakeMed has not, and cannot, demonstrate that the proposed service area is in need of the project.

Besides the service area problems and the existing OR capacity in the immediate area of the proposed project, WakeMed operates a freestanding emergency department ("FSED") in Garner. WakeMed opines that locating a new hospital 0.6 miles from its FSED will benefit patients who need higher acuity services following a visit to the FSED. WakeMed's application does not demonstrate nor sufficiently project that any of its FSED patients have such high acuity that it is necessary to propose a hospital within such proximity.

WakeMed posits that data "demonstrates that throughout over four years of OR need determinations in Wake County, only 28.6 percent of OR approvals were granted to acute care hospitals (4 of 14 awarded ORs), even though much of the generated need has been based on hospital utilization. It is imperative that the OR need in the 2022 SMFP be awarded to a hospital to meet the ongoing demand for hospital-based surgery, including higher acuity outpatient surgery and inpatient surgery." (WakeMed app., p. 57). This claim is not supported by the information in the WakeMed application. WakeMed's statement is not only inconsistent with data showing an upward trend of patients utilizing ASCs, WakeMed provides insufficient data to support that a hospital OR is needed for "higher acuity outpatient surgery and inpatient surgery." WakeMed can add PRs with no CON approval. It can build, equip, and staff the PRs identically to ORs to meet any needs for inpatient surgical services.

For these reasons, for the reasons cited above related to Policy GEN-3, and for other reasons the Agency may discern, WakeMed's proposal is not conforming to Criterion (3).

CRITERION (4)

(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.**

WakeMed does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need based on:

- WakeMed does not demonstrate the need for its proposed project, or that projected utilization is reasonable and adequately supported. See discussions about need and projected utilization under Criterion (3) above. A project that does not provide reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- WakeMed does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. See discussion regarding financial feasibility under Criterion (5) below. WakeMed does not demonstrate that developing the project is financially feasible and thus, cannot demonstrate the proposed alternative is the most effective alternative to meet the need.
- WakeMed does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. See discussion about unnecessary duplication under Criterion (6) below. An unnecessarily duplicative project cannot be the most effective alternative to meet the need.
- WakeMed does not provide credible information to explain why it believes its proposed project is the most effective alternative.
- Assuming the proposed hospital is needed, WakeMed has not chosen the least costly or most effective alternative to arrange surgical services for the proposed hospital. The best alternative is to transfer two for WakeMed's 41 licensed ORs in Wake County to the proposed hospital and relabel the vacated ORs as PRs with no change in their use. This alternative was accepted by the Agency for the Novant Health Ballantyne application.[39] For this new hospital, Novant transferred two ORs from a Novant ASC. Ballantyne had a new dedicated C-Section OR, but those ORs are not subject to SMFP need determinations.
- As discussed above, the total project cost of $214 Million is not a cost-effective way to serve the small number of patients projected to be served and in an area that does not have a need for the proposed service.
- WakeMed is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (4).

[39] Project ID # F-01165218

CRITERION (5)

(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's projected utilization is not reasonable and adequately supported for all the reasons discussed above as to Criterion (3). It is unreasonable to assume that an unneeded project in an area with sufficient OR access will have long-term financial feasibility. As projected revenues and expenses are based in part on projected utilization, WakeMed's projected revenues and expenses are also questionable, rendering the WakeMed application non-conforming to Criterion (5). See Criterion (3) discussion above.

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (5).

CRITERION (6)

(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 explicitly acknowledges that the proposal will "focus on serving the patients already choosing WakeMed for their care." WakeMed application, p. 130. This statement demonstrates an inherent duplication of services as WakeMed only intends to shift its current patients among its own facilities, rather than propose to serve all residents of Wake County, its "primary service area," or its "secondary service area."

The proposed hospital will unnecessarily duplicate existing ED and ancillary services at WakeMed's FSED. The immediate area has sufficient access to outpatient ORs as well as access to UNC Health Johnston, which falls within WakeMed's "primary service area."

For the reasons explained throughout these Comments, WakeMed did not adequately demonstrate projected utilization based on reasonable and adequately supported assumptions. Because the WakeMed utilization is questionable, the applicant does not adequately demonstrate that its project

as proposed is needed. Therefore, WakeMed does not demonstrate its conformity with Criterion (6).

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (6).

CRITERION (7)

(7)	**The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.**

The WakeMed application does not demonstrate conformity with Criterion (7).

The WakeMed application shows that the proposal will require ~115 FTE RN positions and 367 FTEs by project year 3. Given the ongoing critical shortages of clinical staff, it is unreasonable to assume that there is sufficient manpower to operate the proposed project. WakeMed fails to demonstrate how it will appropriately staff the proposal full time.

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (7).

CRITERION (13)

(13)	**The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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.**

The WakeMed application does not demonstrate conformity with Criterion (13).

The WakeMed application cites the payor mix of its Raleigh campus in the context of meeting the needs of the medically underserved. However, the WakeMed application does not demonstrate how it is reasonable to utilize the payor mix of the Raleigh campus given that the proposed project is in southeastern Wake County and will serve a large portion of Johnston County.

In its application, WakeMed states all service components with the exception of the Emergency Department will assume the same payor mix as patients from the proposed service area that received inpatient care at any WakeMed hospital in FY 2022.[40] Although WakeMed notes it excludes service lines that will not be offered at the proposed Garner hospital, it still adopts payor percentages for a different patient acuity level and socioeconomic status than those who will receive care at the Garner location. WakeMed also leaves out the large number of outpatient surgery cases it performs in its payor mix estimate. For WakeMed's Raleigh and Cary facilities, ambulatory cases accounted for over 57 percent of surgeries in licensed ORs in FY 2021.[41] Estimating OR payor mix solely on inpatient cases is not an accurate method for predicting utilization by underserved populations.

It is unreasonable to think that the proposed location of the project and the proposed service areas have similar socioeconomic makeups to the payor mix of the Raleigh and Cary campuses. This ignores the different types of services a tertiary hospital offers versus a community hospital, and the differences in utilization at WakeMed's Raleigh and Cary campuses versus southeast Wake County and Johnston County.

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (13).

CRITERION (18a)

(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.**

The WakeMed application does not demonstrate conformity with Criterion (18a).

The application says the proposed hospital will only serve existing WakeMed patients. If so, it will have no positive impact on competition because it does not plan to compete for new patients with other providers. It will have no benefits of cost-effectiveness, access, or quality.

[40] CON Application # J-012264-22, p.223.
[41] WakeMed Raleigh 2022 LRA, p. 12; WakeMed Cary LRA, p. 12.

If the WakeMed application is approved, it will negatively affect competition by preventing approval of other new providers in Wake County that will compete with WakeMed for patients.

For these reasons and such others as the Agency may discern, the WakeMed application is not conforming with Criterion (18a).

PERFORMANCE STANDARDS: 10A N.C.A.C. 14C.2103

(a)	**An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.**
(b)	**The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.**

WakeMed does not adequately demonstrate the need for the proposed project, or that projected utilization is reasonable and adequately supported. The full discussion regarding analysis of need and projected utilization is found in Criterion (3) and incorporated by reference.

Because WakeMed does not demonstrate the need for the proposed project or that projected utilization is reasonable and adequately supported, the applicant cannot demonstrate the need for the one new OR based on the OR Need Methodology in the 2022 SMFP. Therefore, the application is not conforming with this Rule.

COMMENTS SPECIFIC TO UNC REX HOSPITAL

NON-CONFORMITY OF THE UNC REX HOSPITAL ("Rex") APPLICATION WITH THE REVIEW CRITERIA

CRITERION (1)

> **(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.**

While adding two ORs is consistent with the 2022 SMFP Need Determination, the Rex application does not demonstrate consistency with Policy GEN-3. Therefore, it does not conform to Criterion (1).

The Rex application shows inpatient surgery volume has been declining at Rex with a corresponding increase in outpatient procedures. As stated in the application, "an increasing number of surgical cases in Wake County and North Carolina are shifting to the outpatient setting, partially driving the increase in outpatient volume and concurrent decrease in inpatient value." (Rex app., p. 45). This is true for Rex Hospital which has seen inpatient surgery volume decline, with inpatient cases falling 4.1% annually between 2016 and 2022. (Rex app., Form C Assumptions and Methodology, p. 3). The Rex application does not explain how adding two ORs to its existing facility will enhance access for patients with limited financial services, when performing outpatient surgeries in a hospital setting instead of an ASC will increase costs for patients and insurers.

Despite these acknowledgements, Rex states it "firmly believes that the need for additional operating room capacity in Wake County is specific to hospitals…." (Rex app., p. 40). This belief contradicts the clear trend of patient preference for non-hospital, outpatient settings, both regarding patient convenience and lower costs for patients and insurers. Furthermore, Rex Surgery Center of Cary, UNC Rex Holly Springs Hospital, and Raleigh Orthopaedic Surgery Center, which are part of UNC Health system in Wake County, have capacity for additional outpatient procedures, particularly at Rex Surgery Center of Cary.

Holly Springs Hospital and Rex Surgery Center of Cary have capacity for additional outpatient procedures, Holly Springs Hospital's surgical capacity is likely understated due to use of UNC Rex hospital's case times. Holly Springs Hospital opened in November 2021 and is operating under the same license as UNC Rex Hospital. As a new hospital, it is treating less acute patients and performing fewer complex surgeries than UNC Rex. Rex even states that Holly Springs Hospital "should" provide sufficient capacity, implicitly acknowledging ample capacity without concern

for overutilization. *See* Rex Application, p. 78 ("…its projected utilization demonstrates that its three approved operating rooms should provide sufficient capacity for that facility for the near term.")

The Rex application does not demonstrate consistency with Policy GEN-3. Therefore, it does not conform to Criterion (1).

CRITERION (3)

(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 Hospital can expand and renovate its surgical capacity without approval of a new OR CON. Rex proposes to renovate a PR and other conference room space to develop two new ORs. If Rex labels the rooms as PRs instead of ORs it can implement the project without a CON.

Rex acknowledges it is using PRs for surgical cases. Although Rex projects a need for 2.2 ORs across all its facilities, the need calculation counts "potential operating room cases." In its application, Rex explains:

"Of note, Raleigh Orthopaedic Surgery Center's operating room capacity constraints have further been exacerbated by the relocation of one operating room to Raleigh Orthopaedic Surgery Center-West Cary. Specifically, due to operating room capacity constraints, Raleigh Orthopaedic Surgery Center surgeons have been performing a significant number of surgical cases in procedure rooms that are appropriate for an operating room, including arthroscopy and arthroplasty cases (over 1,000 annually in recent years) as well as most of its cases other than hand cases, which have shorter case times. **These surgical cases performed in procedure rooms are referred to as potential operating room cases in the discussion below as it is the desire and intention of the surgeons to perform them in operating rooms, subject to sufficient capacity.** The number of potential operating room cases and historical operating room cases at Raleigh Orthopaedic Surgery Center increased 1.0 percent annually from SFY 2019 to SFY 2021, as shown below."

Rex app., Form C Assumptions and Methodology, p. 15 (emphasis added).

Another way of saying "potential operating room cases" is cases appropriately and safely performed in a PR. One must assume that Rex surgeons are not performing procedures in PRs unless they are sized, equipped, and staffed appropriately for the procedures performed. The

"desire and intention" to perform such procedures in an OR rather than a PR puts form over substance when not required by the State or any cited authority.

As Rex's project cost exceeds $2,000,000, it must give the Agency notice, but after giving notice its project is statutorily entitled to an exemption from CON review.[42] By renovating a PR and adding a PR, Rex would not be adding a regulated service or otherwise undertaking an activity requiring a CON. The Rex application documents no practical or legal reason to designate these rooms as ORs. The Agency cannot approve the Rex application when no CON is needed for Rex to perform and fulfill the representations in its application.

Unlike Oakview, Rex can perform and fulfill its representations without an OR CON approval.

- A CON is only required for a "new institutional health service" ("NIHS") as defined in the CON Law[43];
- An existing hospital can develop and increase surgical services without OR CON approvals because the CON Law does not define a provider's development or increase in surgical services as an NIHS;
- And an existing hospital can add or renovate physical spaces to offer more surgical care by adding PRs without OR CON approvals because the development, establishment, increase in the number or relocation of PRs is not as an NIHS;
- The CON Law authorizes statutory exemptions from CON review upon the provision of notice and Rex would be entitled to avail itself of such an exemption;
- Rex can perform and fulfill its application representations by expanding surgical offerings by performing surgical procedures in PRs *without approval of its OR CON application*.

The Agency has repeatedly confirmed that adding a PR in a licensed facility does not require *a CON*.

- In 2012, the Agency confirmed that PRs in licensed ASCs and hospitals are only regulated to the extent of ensuring compliance with Life Safety Code provisions and using or establishing a PR does not require "any determination from the [CON] Section." *See* Exhibit G.
- In response to a 2017 inquiry by North Carolina Specialty Hospital ("NCSH"), the Agency confirmed NCSH could develop an additional PR without a CON. *See* Exhibit H.

[42] Expenditures exceeding $2 million will be exempt from review, on provision of notice, if solely to renovate an existing health service on the facility's main campus without changing its bed capacity or adding regulated services. N.C. Gen. Stat. § 131E-184.
[43] N.C. Gen. Stat. § 131E-176–178.

- In response to a 2019 inquiry from Triangle Orthopaedic Surgery Center ("TOSC"), the Agency confirmed TOSC could add two new PRs without a CON. *See* Exhibit I.
- The Agency's Hospital License Renewal Application form acknowledges that hospitals can provide surgical services in PRs "which are not licensed as operating rooms … but are used for performance of surgical procedures." *See* 2022 Hospital License Renewal Application, Sections F.9.c. and F.9.f., attached as Exhibit J.

Agency witnesses, including Senior Project Analyst Michael McKillip, have testified on the Agency's position that PRs can be added *without a CON*. (Such testimony was elicited by counsel for WakeMed.) *See* Excerpts of the June 2020 Deposition of Mr. McKillip, attached as Exhibit K.

> *… development of procedure rooms are not considered a new institutional health service under the statute. So applicants, in my experience, can develop them without a Certificate of Need through – just by obtaining an exemption letter.*
>
> (Michael McKillip, Vol. 2, p. 265)

Mr. McKillip also testified that the Agency does not limit how PRs are constructed, equipped, or staffed. *Id.* In short, PRs can be constructed, equipped, and staffed identically to ORs and any surgery procedure that can be done in an OR can be done in a PR. *Id.* at p. 275.

A PR can be functionally equivalent to an OR. The number of facilities which provide surgical services with a combination of OR and PR capacity show North Carolina providers can and do use PRs in the same fashion as ORs. Existing providers of surgical services are in an enviable position. Under current law, hospitals and ASCs can expand surgical capacity without new OR CON approvals by adding PRs to their existing or approved facilities or to a proposed hospital or ASC. A provider with multiple ORs in a county can relocate one or more of its ORs to develop a new ASC or hospital without CON approval for additional ORs. A provider can designate the vacated ORs as PRs and continue to provide the same surgical services as before.

The only applicant who needs CON approval of a new OR is an ASC applicant with no existing ORs in a county. Only new market entrants face a true barrier-to-entry under current CON Law. Oakview's important ophthalmic ASC will be an option for patients in the area only with CON approval of an OR. For Oakview, unlike Rex, the OR CON is an essential legal requirement.

Rex's application required it to certify its intent to carry out its project as proposed. Thus, one must assume the Rex project is intended for its stated purpose and not to prevent the development of competing ORs nor to "stockpile" ORs that can later be deployed to develop new ASC locations in the service area. Under North Carolina CON Law and the corresponding licensure statutes, Rex can implement its proposed project *without the OR CON approvals it requests.* Because Rex can perform and fulfill its representations without OR CON approvals, the Agency has no authority or legal basis exists to grant Rex's application for additional ORs.

Despite its large and growing population, determinations of need for new ORs in Wake County have been infrequent, with few or none shown in a typical planning year. Awarding an OR CON to Rex, an applicant that does not require such an approval for its project, would squander a rare chance to add needed OR capacity for Wake County residents.

The award of OR CON approvals to Rex would only serve to "place a different label" on rooms which, with some unregulated renovations, Duke Health can already use to perform surgical services. Patients in Wake County who need surgical services will be no better served by Rex whether the spaces are labeled as "OR" or "PR."

However, Oakview cannot develop its proposed ASC without CON approval of one OR. If the Agency approves the Rex OR application, it cannot approve Oakview or other new providers. Approving the Rex OR application would reduce competition from a new provider in Wake County.

Rex cannot justifiably claim it cannot expand its surgical services without new OR CON approvals. Rex has the lawful ability, *without OR CON approvals*, to:

- Develop or establish PRs (by renovation or new construction) built, equipped, and staffed in a fashion identical to their existing or approved ORs in Wake County;
- Perform surgical procedures in PRs in a manner designed to ensure the delivery of safe, quality surgical services.

Nothing justifies the award of OR CON approvals to Rex when nothing in its application establishes that such CON approvals are necessary for it to perform or fulfill its stated intentions to expand surgical capacity in Wake County.

Specifically, in its application as filed, Rex:

- Cites no law or regulation (whether North Carolina or Federal) which requires certain types of surgical cases to be performed in an OR instead of a PR;
- Does not represent that any payor (government or commercial) has imposed a requirement for reimbursement that would dictate that certain surgical cases be performed in an OR instead of a PR;
- Cites nothing indicating that an OR "label" is needed to secure more dollars in reimbursement than would otherwise be received for the same surgical services absent the OR "label;"
- Does not argue that an OR CON is needed to renovate and/or build a room of a desired size or with any certain equipment or to employ any specialized staff;

- Identifies no "standard of care" or clinical or operational standard or expectation governing their facilities or their medical staffs that would require certain cases to be performed in an OR instead of a PR.

If Rex sought to justify approval of its OR application based on any law, regulation, or authority that would require an OR CON, the burden was on Rex to explain that basis in its application. The Rex application, as filed, cannot now be amended to include citation to any of the above as the deadline for the submission of application materials has now passed.

Reasonable and adequately supported utilization projections are required to show need for a proposed project. If projected utilization is not reasonable and adequately supported, then need for the proposal must be questioned.

The Rex application fails to demonstrate need for the population as described below and, therefore, is not confirming with Criterion (3).

The Wake County population has demonstrated a clear preference for ASCs as opposed to hospital outpatient departments. Rex admits as much and fails to demonstrate how adding two hospital-based ORs, in a more costly setting, will serve low-income persons or other underserved groups. ASC facilities perform outpatient surgery at lower cost and with better quality outcomes than hospital ORs. With available capacity in UNC Rex outpatient facilities in Wake County, it is unreasonable to propose the addition of two hospital ORs when demand is declining in favor of non-hospital settings, and hospital-based services are more costly.

Rex's projections indicate that shifting operating room cases from Raleigh Orthopaedic Surgery Center ("ROSC") will free up substantial operating room capacity at ROSC that is not projected to reach current volumes for more than five years.

Projected Raleigh Orthopaedic Surgery Center Utilization after Shifts

	SFY23	*SFY24*	*SFY25*	*SFY26*	*SFY27*
Operating Room Cases	3,528				
Potential Operating Room Cases	1,997				
Total Operating Room Cases Prior to Shifts	**5,525**	**5,721**	**5,925**	**6,135**	**6,353**
Operating Room Cases to Shift to Garner		-1,634	-1,830	-2,031	-2,067
Operating Room Cases to Shift to West Cary	-1,092	-1,136	-1,136	-1,136	-1,136
Raleigh Orthopaedic Surgery Center Operating Room Cases	**2,436**	**2,951**	**2,959**	**2,968**	**3,151**
Total Procedure Room Procedures Prior to Shifts	**3,021***	**1,060**	**1,098**	**1,137**	**1,177**
Procedure Room Procedures to Shift to Garner		-209	-234	-260	-264
Procedure Room Procedures to Shift to West Cary	-143	-148	-153	-159	-164
Raleigh Orthopaedic Surgery Center Procedure Room Procedures	**2,878**	**703**	**710**	**718**	**748**

*Includes both potential operating room cases and procedure room procedures to remain in procedure rooms.

If ROSC is appropriately and safely performing procedures in PRs, those procedures can continue to be appropriately and safely performed in PRs, not ORs. Thus, the Rex application effectively overstates its OR projections at ROSC by roughly 2,000 cases per year.

Rex's Form C.3b calculates "Total Surgical Hours / Standard Hours per OR per Year" to equate to a "need" of 3.3 ORs based on this overstated projection. If one removes the approximate 2,000 cases that Rex labels as "potential operating cases" from the Form C.3b calculation (subtracting 2,000 from 3,151 operating room cases), the "Total Surgical Hours/Standard Hours per OR year" equates to a need of 1.2 ORs (not 3.3 as stated in the application). This directly impacts the underlying need for two additional ORs across Rex-related facilities.

	UNC REX Hospital	*UNC REX Holly Springs Hospital*	*REX Surgery Center of Wakefield*	*REX Surgery Center of Cary*	*Raleigh Orthopaedic Surgery Center*	*Raleigh Orthopaedic Surgery Center-West Cary*	*Orthopaedic Surgery Center of Garner*	*Total*
Total Surgical Hours / Standard Hours per OR per Year	27.2	2.3	3.5	2.5	3.3	1.0	1.8	41.7
Existing and Approved OR Capacity	25	3	2	4	4	1	1	40
OR Deficit/(Surplus)	**2.2**	**(0.7)**	**1.5**	**(1.5)**	**(0.7)**	**0.0**	**0.8**	**1.7**

Rex's Form C Assumptions and Methodology show ROSC having a surplus of 0.7, and without shifting "potential operating room cases," the surplus, based on the 2,000-case deduction outlined above, becomes 2.8 ORs. All Rex facilities have a net surplus of 0.4 ORs. [44] This shows Rex has no need for additional ORs. Rex can "shift" cases between ORs and PR and can add PRs at any time. Rex has no need for approval of a CON for two new ORs. The Agency should use the 2022 Need Determination to award ORs that will be consequential in meeting the health care needs of the residents of Wake County and not simply serve to relabel spaces as Rex asks.

For these and other reasons the Agency may discern, the Rex application is not conforming with Criterion (3).

CRITERION (4)

(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.

[44] This is true, even without addressing the large increase in utilization between state fiscal year 2019 and state fiscal year 2020 that results in the deficit of ORs at Rex Wakefield. Rex does not explain the large increase in utilization. Without it, the system does not have a need for the proposed ORs.

Rex did not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need, because its application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Rex does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need based on:

- Rex does not demonstrate the need for its proposed project, or that projected utilization is reasonable and adequately supported. *See* discussions about need and projected utilization under Criterion (3) above. A project that does not provide reasonable and adequately supported utilization projections is not the most effective alternative to meet the need.
- Rex does not demonstrate that the financial feasibility of the proposal is reasonable and adequately supported. *See* discussion regarding financial feasibility under Criterion (5) below. Rex does not demonstrate that developing the project is financially feasible and thus, cannot demonstrate the proposed alternative is the most effective alternative to meet the need.
- Rex does not demonstrate that the proposed project is not an unnecessary duplication of existing or approved health service capabilities or facilities. *See* discussion about unnecessary duplication under Criterion (6) below. An unnecessarily duplicative project cannot be the most effective alternative to meet the need.
- Rex has not provided credible information to show it proposed the most effective alternative to meet its stated need. The most effective alternative is to renovate and add PRs labeled as PRs. This adds the same surgical capacity as if the rooms were labeled ORs and avoids the expense and delays of the CON process.
- Rex has not adequately demonstrated that the purported need for two additional ORs cannot be met by renovating and adding PRs, nor has Rex shown that its proposal is the least costly or most effective. As discussed under Criterion 3 above, Rex has multiple outpatient facilities with capacity to address patient demand for surgical services. Outpatient facilities are less costly and more effective for meeting the current needs of the population to be served. Rex has failed to show that its proposal is the most effective alternative when it has capacity in its facilities and can effectively utilize its existing ORs and PRs to meet patient demands.
- Rex is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

For these reasons and such others as the Agency may discern, the Rex application is not conforming with Criterion (4).

CRITERION (6)

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

Rex's proposed addition of two ORs will result in unnecessary duplication of its facilities. As discussed under Criterion 3, Rex has multiple facilities which can be used to "shift" cases between facilities, and "shift" cases between ORs and PRs. To be awarded more ORs, a scarce resource in Wake County, based on a "desire or intention" to perform certain procedures in an OR when those procedures are already being appropriately performed in a PR is the essence of unnecessary duplication. Adding two ORs will unnecessarily duplicate Rex's existing resources, including its hospital-based ORs, and prevent new providers of outpatient surgical services from entering the market and competing to meet patient needs.

For the reasons explained throughout these Comments, Rex did not adequately demonstrate projected utilization based on reasonable and adequately supported assumptions. Because the Rex utilization is questionable, the applicant does not adequately demonstrate that its project as proposed is needed. Therefore, Rex does not demonstrate its conformity with Criterion (6).

For these reasons and such others as the Agency may discern, the Rex application is not conforming with Criterion (6).

CRITERION (18a)

(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.

The Rex application did not demonstrate that its proposal will enhance competition, nor that any enhanced competition, were it to exist, would have a positive impact upon the cost effectiveness, quality, or access to surgical services. As referenced above, unnecessary duplication of resources at Rex Hospital does nothing to enhance competition and will not favorably affect cost effectiveness, quality, or access to services for the Wake County population.

As discussed under Criterion (3), the proposal is not needed and will perpetuate higher costs associated with hospital-based procedures. Additionally, increasing the number of hospital-based ORs does nothing to enhance the ability of freestanding outpatient facilities to offer surgical services at a lower cost to patients and insurers.

Agency approval of the Rex application will prevent the Agency from approving the applications of other new providers and prevent them from competing in Wake County by offering ASC services at lower costs that Rex's hospital-based services.

For these reasons and others the Agency may discern, the Rex application is not conforming with Criterion 18a.

PERFORMANCE STANDARDS: 10A N.C.A.C. 14C.2103

(a) An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.

(b) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

Rex does not adequately demonstrate the need for the proposed project, or that projected utilization is reasonable and adequately supported.

The full discussion regarding analysis of need and projected utilization is found in Criterion (3) and incorporated by reference.

Because Rex does not demonstrate the need for the proposed project or that projected utilization is reasonable and adequately supported, the applicant cannot demonstrate the need for the new ORs based on the OR Need Methodology in the 2022 SMFP. Therefore, the application is not conforming with this Rule.

Failure to Pay the Full Application Fee

The Rex Application cannot be considered in this review cycle because Rex failed to pay the full application fee before the start of the Review Period. The application fee required to accompany a CON application is prescribed by statute:

> *An application fee is imposed on an applicant for a certificate of need…. The application fee is five thousand dollars ($5,000) plus an amount equal to three-tenths of one percent (.3%) of the amount of the capital expenditure proposed in the application that exceeds one million dollars ($1,000,000). In no event may the fee exceed fifty thousand dollars ($50,000).*

See N.C. Gen. Stat. § 131E-182(c).

Because CON application fees are prescribed by statute, neither the CON application form nor any regulation (including 10A N.C.A.C. 14C.0203) may override the mandate of the statute.

Here, Rex did not properly calculate the CON application fee due according to the formula set forth in N.C. Gen. Stat. § 131E182(c). Instead, Rex underpaid by $0.27.

Nothing in the statute permits an applicant to pay—nor the Agency to accept—an application fee rounded downward, such that less than the full amount due is paid. Rex's underpayment appears to have resulted from it following the instructions in the Agency's CON application form/fee sheet. However, the burden rests with Rex to ensure it submits the statutorily required application fee in full, notwithstanding any instructions which may appear in the Agency's application form. The application form/fee sheet specifically references N.C. Gen. Stat. § 131E-182(c); it would not have been difficult for Rex to have referenced the statute before submitting its application.

Rex may argue that this oversight is immaterial or *de minimis*, or otherwise attempt to downplay its underpayment. However, the General Assembly clearly intended the fee to be paid with precision. The statute sets forth a precise formula by which a CON application fee is to be calculated, down to three-tenths of one percent (three decimal places (.003)). And nothing in the statute permits the Agency to impose its own materiality threshold or implement a *de minimis* exception. Nor may the Agency allow Rex to remedy its underpayment at this juncture, now that the Review is underway. *See* 2018 Durham County OR Review (additional application fee due from Southpoint Surgery Center was not received by the Agency by the applicable deadline; the application could not be included in the Review).

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2022 State Medical Facilities Plan, no more than two ORs may be approved for Wake County in this review. Because the six applicants in this review collectively propose to develop nine additional ORs in Wake County, all applications cannot be approved for the total number of ORs proposed.

After considering the information in each application and reviewing each individually against the applicable review criteria, a comparative analysis of the proposals is used to decide which proposals should be approved. A comparative review is required as part of the Agency findings when the total ORs in applications found conforming with the applicable review criteria exceed the number the SMFP allows the Agency to approve. The Agency must then comparatively review the applications and select applications that together request ORs not exceeding the number the SMFP allows the Agency to approve. The Agency may conditionally approve a conforming application for fewer ORs than requested.

Because of the significant differences in types of facilities, number of total ORs, numbers of projected surgeries, types of proposed surgical services to be offered, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if applications were for like facilities of like size proposing like services and reporting in like formats. The analysis of factors and the corresponding conclusions may be impacted by the information included by each applicant and the extent to which data can be compared to draw a conclusion that would be of value in evaluating the competitive applications.

The Agency has developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of the type of service 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
- Competition (Access to a New or Alternate Provider)
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid

- Access by Underserved Groups: Medicare
- Projected Average Net Revenue per Patient, Procedure, Case or Visit
- Projected Average Total Operating Cost per Patient, Procedure, Case, or Visit

Project Analysts have the discretion to apply additional factors based on the type of proposal.

Rex petitioned the State Health Coordinating Council (SHCC) to create an adjusted need determination for six ORs for Wake County in the 2022 State Medical Facilities Plan ("2022 SMFP") to be specifically designated for existing licensed acute care hospitals. The Agency Report on the Rex Petition stated that:

> *The Agency does not support specifically designating OR need determinations for a particular type of facility.*
>
> *Thus, … the Agency recommends denial of the Petition to include a need determination for six ORs to be designated for existing licensed hospitals in the Wake County service area.*
>
> *Rather, the Agency recommends adding a need determination for two ORs in the Wake County service area in the 2022 SMFP*.

The 2022 SMFP accordingly identified a Need Determination for two ORs for Wake County with no designation for a particular type of facility applicant. Any provider was able to apply to develop the two ORs in Wake County. No preference is given to Rex because it petitioned for an adjusted need determination. Each applicant must demonstrate need to develop its project, as proposed.

Conformity to CON Review Criteria

Six applications were submitted seeking ORs in Wake County. Based on the 2022 SMFP Need Determination for two ORs, only a total of two OR CON approvals may be issued. Only applications demonstrating conformity with all applicable Criteria can be approved, and only the Oakview application demonstrates conformity to all Criteria:

Conformity of Competing Applications

Applicant	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular	WakeMed Garner	UNC Rex Hospital
Project ID #	J-012252-22	J-012248-22	J-012261-22	J-012253-22	J-012264-22	J-012260-22
Conforming	Yes	No	No	No	No	No

An applicant that is not conforming to all applicable statutory and regulatory review criteria cannot be approved.

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

Scope of Services

Greatest Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this factor. The ORs proposed to be developed by Rex and WakeMed will be hospital ORs which accommodate numerous types of surgical services, both inpatient and ambulatory. Rex and WakeMed are more effective alternatives with regard to this factor but neither are approvable and, therefore, cannot be effective alternatives.

Broadened Scope of Services

Based on the information in the applications as filed in this review, the "scope of services" factor can also compare which proposals, if approved, will result in a broadened scope of services in the service area.

Oakview proposes a new ASC which will offer Wake County residents a previously unavailable model of care for ophthalmic surgery services. While ophthalmic surgery services are offered in hospitals and some multi-specialty ASCs, Oakview would broaden the scope of services by developing Wake County's first dedicated single-specialty ophthalmic surgery facility.

Triangle Vascular would be the second Vascular Access Center in Wake County; RAC Surgery Center already offers a focused vascular access facility in Wake County. In addition, vascular access services are available at hospitals and some ASCs. Thus, TVC's project would not broaden the scope of services available in Wake County.

KM is described as a multi-specialty ASC with a focus on emergency treatment and surgical removal of kidney stones. There are at least eight ASCs in Wake County already providing urology services in a multi-specialty ASC setting, in addition to hospital and hospital-owned emergency service facilities offering urology care.[45] The other non-urology specialties proposed by KM are likewise offered in several existing and approved multi-specialty ASFs in Wake County.

[45] The existing or approved Wake County ASCs providing Urological Surgery include Duke Garner ASC, Duke Green Level ASC, Rex Surgery Center of Cary, Rex Surgery Center of Wakefield, WakeMed Surgery Center- Cary, Capital City Surgery Center, Holly Springs Surgery Center, and Duke Raleigh ASC. WakeMed Surgery Center – North Raleigh may also include Urological Surgery as a surgical specialty upon opening.

Duke Health seeks to reclassify two approved PRs as ORs at its Green Level ASC. Duke Health's project will not broaden the scope of services to be offered in its approved ASC.

UNC Rex and WakeMed propose hospital ORs but approval of these applications will not broaden the scope of services offered to Wake County residents beyond those currently available in the hospital ORs operated by the UNC Health and WakeMed systems in Wake County. These projects add "capacity" but do not broaden existing service offerings.

Oakview is the most effective applicant to broaden the scope of services offered to Wake County residents. A dedicated single-specialty ophthalmic surgery service is not presently offered in any approved or existing facility in Wake County (nor in any contiguous county). While North Carolina is home to eight single-specialty ophthalmic surgery centers, the closest such center for Wake County residents is in Pinehurst (Moore County), approximately 70 miles from Raleigh. None of the other applicants propose to broaden the scope of services by adding a new service not already available to patients in Wake County. Oakview is the most effective alternative to broaden the scope of services offered in Wake County.

Historical Utilization

The table below shows projected OR need in 2024 for Wake County health systems based on surgical hours as reported in Table 6A of the 2022 SMFP.

Generally, of applicants with reported utilization, the applicant with the highest historical utilization is the more effective alternative with regard to this factor.

Applicant	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular	WakeMed Garner	UNC Rex Hospital
Adjusted OR Planning Inventory	0	0	17	1	41	37
Projected 2024 OR Deficit (Surplus)	n/a	n/a	(0.10)	(0.43)	(2.64)	(1.69)

Source: 2022 SMFP, Table 6B, CON Application # J-012253-22, p. 138.

All applicants, other than KM, have experience providing surgical services in an ASC or hospital in North Carolina or other southeastern states (either directly or via affiliate entities). KM is the least effective alternative regarding this factor.

As the table above shows, each applicant/system with reported utilization has a surplus of ORs in Wake County and is therefore less effective. Oakview is the most effective on this factor.

Geographic Accessibility

Not including dedicated C-Section ORs and trauma ORs, there are 117 existing and approved ORs in Wake County, allocated between 25 existing and/or approved facilities, located as shown in the table below.

Wake County OR Inventory by System

Location	Facility Name	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	Total ORs
Cary	Duke Green Level Hospital	0	0	0	0	2	2
Garner	Duke Garner ASC	0	0	0	0	1	1
Cary	Duke Green Level ASC	0	0	0	0	1	1
Raleigh	Duke Raleigh Hospital	0	0	15	0	-3	12
Raleigh	Duke Raleigh ASC	0	0	0	0	1	1
	Duke Health System Total	**0**	**0**	**15**	**0**	**2**	**17**
Garner	Orthopedic Surgery Center of Garner	0	0	0	0	1	1
Cary	Rex Surgery Center of Cary	0	4	0	0	0	4
Raleigh	Raleigh Orthopedic Surgery Center	0	3	0	0	1	4
Raleigh	Rex Surgery Center of Wakefield	0	2	0	0	0	2
Cary	Raleigh Orthopedic Surgery Center - West Cary	0	1	0	0	0	1
Raleigh	Rex Hospital	4	0	27	-4	0	27
	UNC Health Total	**4**	**10**	**27**	**-4**	**2**	**39**
Cary	WakeMed Surgery Center - Cary	0	0	0	0	1	1
Raleigh	WakeMed Surgery Center - North Raleigh	0	0	0	0	1	1
Raleigh	Capital City Surgery Center	0	8	0	0	-1	7
Raleigh	WakeMed Hospital	8	0	20	-5	0	23
Cary	WakeMed Cary Hospital	2	0	9	-2	1	10
	WakeMed Health Total	**10**	**8**	**29**	**-7**	**2**	**42**
Raleigh	Ortho NC ASC	0	0	0	0	1	1
Raleigh	RAC Surgery Center	0	1	0	0	0	1

Wake County OR Inventory by System (*cont'd*)							
Location	**Facility Name**	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section, Trauma, Burn ORs**	**CON Adjust-ments**	**Total ORs**
Raleigh	Surgical Center for Dental Professionals of NC**	0	2	0	0	0	2
Raleigh	Blue Ridge Surgery Center	0	6	0	0	0	6
Raleigh	Raleigh Plastic Surgery Center	0	1	0	0	0	1
Garner	Valleygate Surgery Center	0	0	0	0	1	1
Raleigh	Triangle Surgery Center	0	2	0	0	1	3
Raleigh	Wake Spine and Specialty Surgery Center	0	0	0	0	1	1
Holly Springs	Holly Springs Surgery Center	0	3	0	0	0	3
	Wake County Total	**14**	**33**	**71**	**-11**	**10**	**117**

Source: Proposed 2023 SMFP, Table 6A. Duke Health inventory includes the Duke Raleigh ASC that was approved in July 2022 (CON # J-012212-22)

OR Resources Per 1,000 Population

Community	2021 Population	Existing & Approved ORs	ORs Per 1,000 Population
Raleigh	469,124	90*	0.19
Cary	176,987	19	0.11
Garner	31,935	3	0.09
Wake County Total	1,150,204	117	0.10

Source: US Census Bureau QuickFacts; Proposed 2023 SMFP, Table 6A.

**Note: Raleigh OR total excludes 3 ORs at UNC Rex Holly Springs Hospital that are licensed at the UNC Rex Main Campus in Raleigh.*

Existing and/or approved facilities offer multiple ORs in Raleigh, Cary, and Garner. Three Garner facilities were recently approved and are under development.

UNC Rex proposes to develop two additional ORs at its existing hospital in Raleigh. Oakview and KM each propose a new ASC in Raleigh. WakeMed proposes to develop two ORs in its proposed hospital in Garner, expanding the services available at its nearby Garner Healthplex. Duke Health

proposes to reclassify two procedure rooms as ORs at its approved ASC in Cary. TVC proposes a new ASC in Cary.

Therefore, with regard to expanding geographic access to surgical services, all of the proposals are equally effective alternatives because they propose to develop the operating rooms in either Raleigh, Cary, or Garner. These communities have existing access to surgical services in existing and approved ORs. The ratio of available OR resources to the total population in these communities is comparable and similar to the overall countywide rate.

Access by Service Area Residents

The 2022 SMFP defines the service area for ORs as *"… the single or multicounty grouping show in Figure 6.1."* Figure 6.1, page 55, shows Wake County as its own OR service area. Wake County is the service area, but facilities may serve residents of counties outside the 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.

Access by Service Area Residents

Applicant	% of Wake County Residents – 3rd Full FY
KM Surgery Center	75.0%
Oakview ASC	69.4%
WakeMed Garner*	67.9%
UNC Rex	63.0%
Duke Green Level ASC	51.1%
Triangle Vascular Center	23.6%

**Origin for outpatient surgery cases, as shown in Table Q-4.g on p. 199*

As the table above shows, KM projects to serve the highest percentage of Wake County residents and Oakview projects to serve the second highest percentage of Wake County residents during the third full fiscal year of operation following each project's completion.

Thus, the application submitted by KM is the most effective alternative and the application submitted by Oakview is the more effective alternative on this factor. However, KM is not approvable and therefore cannot be an effective alternative.

Patient Access to Lower Cost Surgical Services

The Wake County operating room service area currently has 117 operating rooms (excluding dedicated C-Section and trauma operating rooms). These ORs can be licensed as either hospital-

based or under an ASC license. Many outpatient surgery procedures are appropriate for an ASC, as the cost for that service is quite often lower than the same procedure performed in a hospital-licensed OR. The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared IP/OP operating rooms in Wake County.

Wake County Existing and Approved ORs by Type

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs	% OP of Total ORs	Shared ORs	% Shared of Total ORs
Wake County ORs	117	14	12.0%	40	34.2%	63	53.8%

Source: Proposed 2023 SMFP, Table 6A.
**Includes existing and approved operating rooms. Excludes dedicated C-Section and trauma operating rooms.*

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

Percent of Surgery Cases

Wake County Surgical Facility	Type of ORs	Inpatient Cases	Ambulatory (Outpatient) Cases	Total Cases	Percent Ambulatory
Duke Raleigh Hospital	Hospital Shared	3,369	6,575	9,944	66%
Rex Surgery Center of Cary	ASC	--	3,810	3,810	100%
Raleigh Orthopedic Surgery Center	ASC	--	4,126	4,126	100%
Rex Surgery Center of Wakefield	ASC	--	2,325	2,325	100%
Rex Hospital	Hospital Shared	7,631	10,839	18,470	59%
Capital City Surgery Center	ASC	--	6,055	6,055	100%
WakeMed Hospital	Hospital Shared	7,952	11,194	19,146	58%
WakeMed Cary Hospital	Hospital Shared	2,867	3,681	6,548	56%
Surgical Center for Dental Professionals of NC**	ASC	--	360	360	100%
Blue Ridge Surgery Center	ASC	--	4,938	4,938	100%
Raleigh Plastic Surgery Center	ASC	--	303	303	100%
Triangle Orthopedics Surgery Center	ASC	--	2,497	2,497	100%
Holly Springs Surgery Center	ASC	--	2,266	2,266	100%
TOTAL		**21,819**	**58,969**	**80,788**	**73%**

Source: 2022 SMFP, Table 6B.

As the table shows, 73% of the total Wake County surgical cases in FY 2020 were performed as ambulatory (outpatient) surgeries. Wake County has 19 existing and approved ASCs. Ambulatory surgical cases represented 73% of Wake County's FY 2020 total surgical cases, while ASC operating rooms accounted for 33% of the total. ASC-based surgeries are less expensive for payors and patients than hospital-based surgery. Projects proposing the development of ambulatory operating rooms represent a lower cost surgical venue and are a more cost-effective use of ORs than hospital-based projects.

Applicant	**Oakview ASC**	**KM Surgery Center**	**Duke Green Level ASC**	**Triangle Vascular**	**WakeMed Garner**	**UNC Rex Hospital**
OR Type	ASC	ASC	ASC	ASC	Hospital Shared	Hospital Shared
Comparison	More Effective	More Effective	Less Effective	Less Effective	Less Effective	Less Effective

In this batching cycle, however, two of the proposed ASCs are not expected to offer area residents with improved access to a lower cost surgical venue. Duke Health's proposal would relabel two already-approved procedure rooms to operating rooms. This would not expand the surgical capacity at Duke Health. Patients would not incur lower costs for procedures in Duke Health's ORs instead of its PRs. Therefore, Duke Health's project is not an effective alternative for patient access to lower cost surgical care. TVC expects its ASC's volume will primarily be a "shift from the office-based TVA to the licensed TVC ambulatory surgical facility."[46] TVC projects 92% of its year three procedures (2,732 of 2,975) are attributable to shifting patients from a physician's office setting to an ASC setting. An ASC setting is not a lower-cost site of care than a physician's office. Therefore, TVC does not offer an effective choice for providing access to lower cost surgical care.

Oakview and KM are the most effective applications with regard to this factor. Of those, only Oakview is approvable.

Competition (Patient Access to a New or Alternative Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The following table identifies the adjusted planning inventory of operating rooms for each applicant as a percent of the total existing

[46] TVC CON Application, p. 134.

and approved Wake County operating rooms, based on Table 6B of the Proposed 2023 SMFP. Table 6B shows a total of 117 existing and approved operating rooms in Wake County.

ORs in Wake County by Health System/Applicant

Applicant/Health System	Number of ORs	Percent of ORs
Oakview ASC	0	0.0%
KM Surgery Center	0	0.0%
Triangle Vascular Center (Azura Vascular Care)	1	0.9%
Duke University Health System	17	14.5%
UNC Rex Health	40	34.2%
WakeMed	42	35.9%

Source: 2023 SMFP, Table 6B Adjusted Planning Inventory.

As the table above shows, WakeMed Health System controls 36 percent of the existing and approved operating rooms in Wake County, UNC Rex Health System controls 34 percent, and Duke University Health System controls 15 percent. TVC's co-applicant Azura Vascular Care also operates and manages the 1-OR Raleigh Access Center (RAC) in Wake County. Oakview and KM neither own nor operate any existing surgical facilities in the service area, and, therefore, both would be a new provider of surgical services in Wake County. Therefore, with regard to increasing competition for surgical services in Wake County, the applications submitted by Oakview and KM are the most effective alternatives. The applications submitted by WakeMed, UNC Rex and Duke Health are the least effective, as these providers have a large percent of the existing OR inventory in the service area. KM and TVC are not approvable and therefore cannot be effective alternatives.

Access by Underserved Groups

G.S. 131E-183(a)(13) defines "underserved groups" 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.*

Projected Charity Care

The table below shows various metrics relating to projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this factor.

Charity Care (Year 3)	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular
Charity Care $	$322,330	$1,459,754	$1,053,923	$492,882
% of Gross Revenue	2.8%	6.0%	2.3%	1.4%
Number of Cases	150	198	71	75
% of Total Cases	3.0%	4.8%	1.5%	2.5%

Source: CON applications, Section L.4

Charity Care (Year 3)	WakeMed Garner	UNC Rex Hospital
Charity Care $	$4,936,304	$24,051,877
% of Gross Revenue	6.8%	3.1%
Number of Cases	204	615
% of Total Cases	6.8%	2.70%

Source: CON applications, Section L.4

Differences exist in the level of care as some applications propose ORs in hospitals and others in ASCs.

As to the two applicants proposing ORs in hospitals, Rex proposes the highest charity care in dollars and number of cases; WakeMed proposes the highest charity care as a percent of gross revenue and as a percent of total cases. Rex and WakeMed appear to be equally effective as to this factor.

As to the applicants proposing ORs in ASC, KM projects the highest charity care in dollars, the highest charity care as a percent of gross revenue, the highest number of charity care cases, and the highest charity care as a percent of total cases. KM is the most effective alternative among the ASC applications with regard to this factor. However, KM is not approvable. Other than KM, Oakview projects the highest charity care as a percent of gross revenue, the highest number of charity care cases, and the highest charity care as a percent of total cases. Oakview has also committed to participating in the Mission Cataract program, building on US Eye's historical commitment to serving charity care patients. Oakview is the more effective alternative among the ASC applications with regard to this factor.

Projected Medicare

The following table shows various metrics relating to projected Medicare revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicare revenue is the most effective alternative with regard to this comparative factor to the extent the Medicare revenue represents the number of Medicare patients served.

Medicare (Year 3)	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular
Projected Total Medicare Revenue	$3,719,196	$7,316,597	$17,131,645	$10,896,227
Medicare Revenue per Surgical Case	$1,491	$6,286	$5,225	$14,947
% of Gross Surgical Revenue	72.1%	29.9%	41.8%	82.1%
Medicare Cases	3,608	1,206	1,861	2,067
% of Total Cases	72.3%	29.5%	38.8%	69.4%

Source: CON Applications, Sections L.4 and Forms F.2b

Medicare (Year 3)	WakeMed Garner	UNC Rex Hospital
Projected Total Medicare Revenue	$29,938,614	$336,212,919
Medicare Revenue per Surgical Case	$15,121	$14,762
% of Gross Surgical Revenue	41.0%	43.5%
Medicare Cases	1,236	9,315
% of Total Cases	41.0%	40.9%

Source: CON Applications, Sections L.4 and Forms F.2b

Differences exist in the level of care as some applications propose ORs in hospitals and others in ASCs.

As shown in the table above, of the two applicants proposing OR in hospitals, Rex projects the highest total Medicare revenue, the highest Medicare revenue as a percent of gross surgical revenue, and the highest total Medicare cases. WakeMed projects the highest Medicare revenue per case; Rex and WakeMed are comparable as to Medicare cases as a percent of total cases. Rex appears to be the more effective hospital application as to this factor.

Of the applicants proposing ORs in ASCs, Duke Health projects the highest total Medicare revenue; TVC proposes the highest Medicare revenue per surgical case and the highest Medicare revenue as a percent of gross surgical revenue.

Oakview projects the highest number of Medicare cases and the highest number of Medicare cases as a percent of total cases among the applications proposing ORs in ASCs. Oakview projects the second highest number of Medicare cases among all applications in this review; Oakview projects the highest number of Medicare cases as a percent of total cases of all applicants including applications proposing ORs in hospitals and ASCs.

Oakview is the most effective among the ASC applicants as to this factor; Duke Health and TVC are more effective among the ASC applicants as to this factor.

Projected Medicaid

The following table shows various metrics relating to projected Medicaid revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicaid revenue is the more effective alternative with regard to this comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served.

Medicaid (Year 3)	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular
Medicaid Total Revenue	$12,397	$499,836	$419,298	$585,576
Medicaid Revenue per Surgical Case	$5	$429	$128	$803
% of Gross Surgical Revenue	0.2%	2.0%	1.0%	4.4%
Medicaid Cases	25	78	283	135
% of Total Cases	0.5%	1.9%	5.9%	4.5%

Source: CON Applications, Section L.4 and Forms F.2b

Medicaid (Year 3)	WakeMed Garner	UNC Rex Hospital
Medicaid Total Revenue	$10,240,535	$35,655,233
Medicaid Revenue per Surgical Case	$5,172	$1,565
% of Gross Surgical Revenue	14.0%	4.6%
Medicaid Cases	423	979
% of Total Cases	14.0%	4.3%

Source: CON Applications, Section L.4 and Forms F.2b

Differences exist in the level of care as some applications propose ORs in hospitals and others in ASCs.

As shown in the table above, of the two applicants proposing OR in hospitals, Rex projects the highest total Medicaid revenue, and the highest total Medicaid cases. WakeMed projects the highest Medicaid revenue per case, the highest Medicaid revenue as a percent of gross surgical revenue, and the highest number of Medicaid cases as a percent of total cases. WakeMed is the more effective applicant for this factor.

Of the applicants proposing ORs in ASCs, TVC projects the highest total Medicaid revenue; Duke Health projects the highest number of Medicaid cases and the highest number of Medicaid cases as a percent of total cases. TVC proposes the highest Medicaid revenue per surgical case and the highest Medicaid revenue as a percent of gross surgical revenue. TVC is the most effective for this factor among applicants proposing ORs in ASCs, while Duke Health is more effective.

Projected Average Net Revenue per Surgical Case/Patient

The following table shows the projected average net revenue per surgical case in the third full fiscal year following project completion for each ambulatory surgery facility. Generally, the application projecting the lowest average net revenue per surgical case is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third-party payor.

Net Revenue Per Case (Year 3)	Oakview ASC	KM Surgery Center*	Duke Green Level ASC	Triangle Vascular
Total Outpatient Surgical Cases	2,495	1,164	3,279	729
Net Revenue for Outpatient Surgical Services	$2,722,058	$7,074,418	$15,663,253	$4,226,955
Net Revenue Per Outpatient Surgical Case	$1,091	$6,078	$4,777	$5,798

Source: CON Applications, Form F.2b
**KM Surgery Center does not provide a breakdown of operating room revenue and total revenue. The calculations of average revenue per OR case are based on total facility revenue and are thus overstated by an indeterminate amount.*

Net Revenue Per Case (Year 3)	WakeMed Garner	UNC Rex Hospital*
Total Outpatient Surgical Cases	1,980	22,776
Net Revenue for Outpatient Surgical Services	$16,377,138	$252,596,640
Net Revenue Per Outpatient Surgical Case	$8,271	$11,090

Source: CON Applications, Form F.2b
**UNC Rex does not provide a breakdown of outpatient surgeries. The figures shown include inpatient surgeries performed in UNC Rex Hospital's shared and dedicated inpatient operating rooms. Net revenue is the average for all surgical cases performed in UNC Rex operating rooms.*

Differences exist in the level of care as some applications propose ORs in hospitals and others in ASCs. The comparison of average revenue per case for the two hospital-based applicants is shown in the second table. As shown in the table above comparing applications proposing ASC-based ORs, Oakview projects the lowest net revenue per surgical case in the third full fiscal year following project completion. Therefore, Oakview is the most effective alternative with respect to net revenue per surgical case.

Projected Average Operating Expense Per Surgical Case/Patient

The following table shows the projected average operating expense per surgical case in the third full fiscal year following project completion for each ambulatory surgery facility. Generally, the application projecting the lowest average operating expense per surgical case is the more effective

alternative to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Operating Expense Per Case (Year 3)	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular
Total Outpatient Surgical Cases	2,495	1,164	3,279	729
Operating Expenses for Outpatient Surgical Services	$2,452,508	$5,076,781	$11,289,982	$2,149,140
Avg Operating Expense Per Outpatient Surgical Case	$983	$4,361	$3,443	$2,948

Source: CON Applications, Form F.2b
** KM Surgery Center does not provide a breakdown of operating room expenses and total expenses. The calculations of average expense per OR case are based on total facility expenses and are thus overstated by an indeterminate amount.*

Differences exist in the level of care as some applications propose ORs in hospitals and others in ASCs. The table below shows the operating expenses and average expense per outpatient surgery case for the two hospital-based applicants.

Operating Expense per Case (Year 3)	WakeMed Garner	UNC Rex Hospital*
Total Outpatient Surgical Cases	1,980	22,776
Operating Expenses for Outpatient Surgical Services	$16,923,587	$205,748,067
Avg Operating Expense Per Outpatient Surgical Case	$8,271	$9,034

Source: CON Applications, Form F.2b
**UNC Rex does not provide a breakdown of outpatient surgeries. The figures shown include inpatient surgeries performed in UNC Rex Hospital's shared and dedicated inpatient operating rooms. Operating expenses are for all surgical cases performed in UNC Rex operating rooms.*

As the table above shows, Oakview projects the lowest operating expense per surgical case of all ASC and hospital applicants in the third full fiscal year following project completion. Oakview is the most effective alternative with respect to operating expense per surgical case.

SUMMARY

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. Factors are listed in the order discussed above but not necessarily in the order of importance.

Comparative Factor	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular Center	WakeMed Garner	UNC Rex Hospital
Conformity with Review Criteria	Yes	No	No	No	No	No
Scope of Services – (Greater Scope)					Most Effective	Most Effective
Scope of Services – (Broadened Scope)	Most Effective					
Geographic Accessibility	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective
Patient Access to Lower Cost Surgical Services	Most Effective	Most Effective				
Historical Utilization	Most Effective		More Effective	More Effective	More Effective	More Effective
Competition/Access to a New Provider	Most Effective	Most Effective				
Access by Service Area Residents	More Effective	Most Effective				
Access by Underserved Groups:						
Charity Care: ASC Applicants	More Effective	Most Effective				
Charity Care: Hospital Applicants					Equally Effective	Equally Effective
Medicare: ASC Applicants	Most Effective			More Effective		

Comparative Factor	Oakview ASC	KM Surgery Center	Duke Green Level ASC	Triangle Vascular Center	WakeMed Garner	UNC Rex Hospital
Medicare: Hospital Applicants						More Effective
Medicaid: ASC Applicants			More Effective	Most Effective		
Medicaid: Hospital Applicants						More Effective
Projected Average Net Revenue per Case	Most Effective					
Projected Average Operating Expense per Case	Most Effective					

The Oakview application is an effective alternative with respect to Conformity with the Review Criteria and is a most effective alternative for eight factors:

- Conformity with Review Criteria
- Scope of Services – (Broadened Scope)
- Patient Access to Lower Cost Surgical Services
- Historical Utilization
- Competition/Access to New Provider
- Medicare: ASC Applicants
- Projected Average Net Revenue per Case
- Projected Average Operating Expense per Case

And a more effective alternative for two factors:

- Access by Service Area Residents
- Charity Care: ASC Applicants

Oakview is determined to be most effective alternative for eight factors and a more effective alternative for two additional factors.

On the factor "Geographic Accessibility," all applications are equally effective.

The applications other than Oakview are not effective alternatives with respect to Conformity with the Review Criteria and thus are not approvable.

For purposes of the Comments, Oakview notes:

- KM was determined to be a most effective alternative for four factors and was not a more effective alternative for any factor;
- TVC was determined to be a most effective alternative for only two factors and a more effective alternative for only three factors;
- Duke Health was determined to be a most effective alternative for only one factor and a more or equally effective alternative for only two factors;
- Rex was determined to be a most effective alternative for only one factor and a more o effective alternative for only three factors;
- WakeMed was determined to be a most effective alternative for only one factor and a more effective alternative for only one factor.

It is possible to approve the application of Oakview for one OR while approving another applicant for one OR. Alternatively, the Agency may lawfully award only one OR CON approval to Oakview in this review.

CONCLUSION

North Carolina General Statutes § 131E-183 is a determinative limit on the number of ORs that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted in this review would result in ORs in excess of the need determination for Wake County. Based on the review of each application and the Comparative Analysis, Oakview demonstrates conformity and comparative superiority and qualifies for CON approval.

EXHIBIT A

Petition for Adjusted Need Determination for 2018 State Medical Facilities Plan Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients
July 26, 2017

This Petition for Adjusted Need Determination is jointly submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology, PA (the "Practices"), and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care ("Azura"), which operate several outpatient vascular access centers in North Carolina specializing in the management and maintenance of End Stage Renal Disease patients' vascular accesses, which are necessary for life-sustaining hemodialysis treatments.

The Practices and Azura propose an adjusted need determination for a demonstration project to develop two (2) operating rooms in each of the six (6) Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients' vascular accesses. These facilities will improve access to life-sustaining dialysis care, the quality of vascular access care for ESRD patients, and clinical outcomes for these patients.

In addition, because of recent regulatory and reimbursement changes, existing, physician office-based vascular access centers will no longer be sustainable if they cannot become licensed ambulatory surgical facilities and will close, forcing ESRD patients into hospitals. Providing vascular access services in the hospital setting will result in unnecessary use of inpatient resources, unnecessary hospital admissions and increased costs to patients and the health care system, unnecessary delays in a patient's ability to dialyze, exposure to infection risk associated with an inpatient setting, and fragmentation of care. Consequently, providing vascular access services in hospitals will result in much greater expense, and with worse patient outcomes.

Kidney disease statistics for the United States indicate that 1 in 10 adults have some level of chronic kidney disease[1], and individuals with complete kidney failure – i.e., End Stage Renal Disease ("ESRD") – must have either dialysis or a kidney transplant to survive. As of December 31, 2016, 17,387 North Carolina residents were undergoing dialysis for ESRD.[2] These patients must undergo routine, ongoing hemodialysis, in which their blood is filtered through a machine that removes waste products from the blood, and which requires vascular access. Vascular access, including an arteriovenous ("AV") fistula or graft, enables a dialysis machine to access a patient's blood and facilitate the removal and filtration of the blood before it is returned to the patient. While indispensable to hemodialysis treatment, vascular accesses have very high dysfunction rates, with patients being susceptible to clotting, infection, and venous injury. Therefore, dialysis access management and treatment of vascular access complications is critical to an ESRD patient's plan of care. Absent a functioning vascular access, ESRD patients cannot receive dialysis and are at risk of hospitalization, serious complications, and death.

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[1] World Kidney Day: Chronic Kidney Disease. http://www.worldkidneyday.org/faqs/chronic-kidney-disease/.
[2] July 2017 N.C. Semiannual Dialysis Report, Table A.

1. Name, address, email address and phone number of petitioners:

American Access Care of NC, PLLC
American Access Care of NC is an interventional radiology and vascular surgery practice located in Cary.

Eastern Nephrology Associates, PLLC
Eastern Nephrology Associates is a 20-physician nephrology practice headquartered in Greenville and New Bern, serving eastern North Carolina since 1975.

Metrolina Nephrology Associates, PA
Metrolina Nephrology Associates is a 34-physician nephrology practice with offices in Charlotte, Concord, Gastonia, Huntersville, Monroe, Mooresville, and Salisbury, serving the Metrolina area for over 40 years.

North Carolina Nephrology, PA
North Carolina Nephrology (formerly Capital Nephrology Associates and Wake Nephrology Associates) is a 20-physician nephrology practice with offices in Raleigh, Cary, Fuquay-Varina, Zebulon, Smithfield, Louisburg, and Dunn, serving Raleigh and the surrounding counties.

Fresenius Vascular Care, Inc.
Azura Vascular Care is the trade name of Fresenius Vascular Care, Inc., a national network of outpatient vascular care and ambulatory surgery centers that specialize in minimally invasive techniques to treat and manage vascular conditions. Azura-affiliated vascular access centers currently operate in Raleigh, Cary, Greenville, New Bern, Charlotte, Concord and Lenoir, NC.

Address/Email Address/Phone Number of Petitioners:
Azura Vascular Care
Attn: Murat Sor, MD
Chief Medical Officer
muratsor@fvc-na.com
52 East Swedesford Road, Suite 110
Malvern, PA 19355
610-644-8900

2. Statement of requested adjustment, citing provision in proposed SMFP for which adjustment is proposed.

The Practices and Azura request an adjusted need determination for the development of two (2) operating rooms in each Health Service Area in the State, exclusively to provide vascular access procedures for end stage renal disease (ESRD) patients in separately licensed ambulatory surgical facilities. This change would constitute a change to Chapter 6 of the SMFP, and would read as follows:

Table 6___: Renal Single Specialty Ambulatory Surgical Facility Demonstration Project

Operating Room Service Area	Operating Room Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
HSA I	**2***		
HSA II	**2***		
HSA III	**2***		
HSA IV	**2***		
HSA V	**2***		
HSA VI	**2***		

* Need determination is pursuant to the Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project.

Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project
In response to a petition from several physician practices and Azura Vascular Care, an adjusted need determination for Vascular Access Single Specialty Ambulatory Surgical Demonstration Projects (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state serves the access and value Basic Principles by avoiding a concentration of Vascular Access Ambulatory Surgical Centers in one geographic area. There is a need determination for up to two operating rooms in each of the six Health Service Areas statewide, which operating rooms must be located in separately licensed vascular access single specialty ambulatory surgical facilities.

Applicant(s) shall demonstrate in the certificate of need application that the proposal will meet each criterion set forth below.

	Criterion	Basic Principle and Rationale
1	The application shall contain a description of the percentage ownership interest in the facility by each vascular surgeon and nephrologist.	Value – Implementing the innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
2	The proposed facility shall provide open access to non-owner and non-employee nephrologists and vascular surgeons.	Access – Services will be accessible to a greater number of ESRD patients if the facility has an open access policy for nephrologists and vascular surgeons.
3	The operating rooms shall provide only vascular access creation and management procedures for ESRD patients.	Value – Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
4	The proposed facility shall be certified by the Centers for Medicare and Medicaid Services (CMS), and shall commit to continued compliance with CMS conditions of participation.	Access – Requiring services to low income and medically underserved patients promotes equitable access to the services provided by the demonstration project facilities.
5	The proposed operating rooms shall provide care to underserved ESRD patients. At least 60% of the total number of patients served	Access – Requiring Service to Medicare patients promotes equitable access to the services provided by the demonstration project

	each year shall be Medicare or Medicaid recipients.[3]	facilities.
6	The proposed facility shall obtain accreditation after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or the Joint Commission (TJC), and shall commit to continued compliance with their respective standards.	Quality – Adherence to certification processes ensures that the facility is committed to meeting the generally accepted industry standards for quality and safety for their patients.
7	Health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital bylaws, are required to establish or maintain hospital staff privileges with at least one hospital with which the proposed facility has a transfer agreement in place.	Quality - Encouraging health care professionals to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps ensure the continued viability of community based hospital resources.
8	The proposed operating rooms shall meet all reporting, monitoring and evaluation requirements of the demonstration project set forth by the Agency.	Safety and Quality, Access, Value - Timely monitoring enables the Agency to determine whether proposed projects are meeting criteria and to take corrective action if approved applicants fail to meet criteria.
9	For each of the first three full federal fiscal years of operation, the applicant(s) shall provide the projected number of procedures in each proposed operating room for the following payor types: (i) charity care/self-pay; (ii) Medicare; (iii) Medicaid; (iv) TRICARE; (v) private insurance; and (vi) payment from other sources.	Access - Requiring service to a wide range of patients promotes equitable access to the services provided by the demonstration project facilities.
10	The performance standards in 10A NCAC 14C.2103 would apply.	Value - Performing at least a minimum number of outpatient procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.

To ensure that the demonstration project facilities meet all three Basic Principles, each selected site shall be required to provide annual reports to the Agency showing compliance with the criteria in Table ___ of the 2018 State Medical Facilities Plan. The Agency shall specify the report components and format. The Agency will produce an annual summary of each facility's annual report, and will evaluate the demonstration project after it has been in operation for three full federal fiscal years. Depending on the results as presented by the Agency, the State Health Coordinating Council shall consider whether to permit expansion beyond the original demonstration project sites.

[3] By law, Medicare is the designated ESRD insurance program. As a result, ESRD patients of any age qualify for Medicare if they are eligible for Social Security disability, and Medicare remains the primary insurer for most ESRD patients. *See* Social Security Administration Program Operations Manual System, § DI 45001.001, "End Stage Renal Disease (ESRD) Entitlement Provisions," *available at* http://policy.ssa.gov/poms.nsf/lnx/0445001001.

3. Reasons for the Proposed Adjustment:

An adjusted need determination should be included in the 2018 SMFP in order to preserve access to life-saving, high-quality care historically provided by physician office-based vascular access centers that provide dialysis access maintenance services. Allowing for existing vascular access centers to become licensed ASCs will enable the Practices and other providers to continue serving the vulnerable ESRD patient population. The demonstration project would also enable the development of new centers in areas not yet served. Therefore, allowing this petition will improve access to and quality of care, reduce the cost of care, and critically, keep this vulnerable patient population's episodic vascular access care out of the hospital setting.

Clinical Background:

ESRD, commonly known as kidney failure, currently affects about 650,000 Americans and is growing nationally at 5% per year. Many ESRD patients suffer from underlying disease complications and multiple co-morbidities, resulting in poor health outcomes, high rates of hospital admission and readmission, and higher mortality rates. ESRD is predominantly caused by high blood pressure and/or diabetes and disproportionately affects minorities and lower socioeconomic classes. An ESRD patient has two options for survival: kidney transplantation or dialysis treatment. The predominant dialysis modality is hemodialysis, which patients typically receive in outpatient dialysis clinics three times a week for four hours at a time. At each hemodialysis treatment, a dialysis machine removes a large volume of blood from the patient's body, filters the blood through a dialyzer to mimic the function of the kidneys, and returns the filtered blood to the patient. A necessary component of hemodialysis treatment is the patient's vascular access, a shunt that accesses the patient's body blood.

Vascular accesses are surgically created vein and artery blood shunts that fall into three categories: central venous catheters ("CVCs"), arteriovenous grafts ("AVGs"), or arteriovenous fistulas ("AVFs"). See **Exhibit A**. CVCs and AVGs are synthetic shunts, whereas AVFs are constructed from the patient's own veins and arteries. CVCs are typically the first access a dialysis patient will receive because catheters allow immediate access, whereas AVGs and AVFs require anywhere from 3 to 6 months post-surgery to mature into functioning accesses. Despite the maturation period, AVGs and AVFs are preferable to CVCs because CVCs have the highest infection rates among available accesses. CVCs have a 20% infection rate, AVGs a 10% infection rate, and AVFs a 0.5% infection rate. All vascular accesses, however, are susceptible to high dysfunction rates due to blockages, blood clots, and infection. The average dialysis patient experiences 2.2 to 2.5 access interventions per year in order to maintain a well-functioning access. For ESRD patients on hemodialysis, vascular access is a lifeline – but also an Achilles' heel. Without a functioning vascular access, patients cannot receive hemodialysis and are at risk of serious complications and death within 1-2 days.

Historically, dialysis access creation and maintenance required inpatient surgery, and the creation of vascular accesses is still performed primarily in a hospital setting. But since the early 2000s, dedicated, physician office-based vascular access centers have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within

hours. Vascular access maintenance procedures are minimally invasive and use x-ray fluoroscopy to guide wires and catheters through blood vessels. Vascular access procedures for ESRD patients include angioplasty (to unblock clogged vessels at the access site), dialysis catheter management, thrombectomy, and stent placement. Azura-affiliated facilities' policy is to accommodate patients on a same-day basis, and in any event no later than the following day.

While vascular access centers are a demonstrated superior care model, new reimbursement rules have made the operation of vascular access centers in the physician office setting unsustainable, as detailed below. Therefore, licensed, vascular access ambulatory surgery centers ("vascular ASC") are necessary to preserve access to timely, cost effective care. Moreover, providing care in a licensed ASC would allow vascular ASCs to create vascular accesses, which are currently done in hospitals, in a less-expensive ambulatory setting and continue to keep overall health care spending on ESRD patients down by avoiding needless hospital admissions.

Dedicated Vascular Access ASCs Will Achieve Better Outcomes

Purpose-built vascular access centers like those operated by the Practices and Azura have a proven track record of improved clinical outcomes as a result of specialization and better coordination of care.

- A 2006 study examining the implementation of a vascular access center offering both vascular access creation and maintenance services in Phoenix, AZ, with a dialysis patient population of nearly 6,000, documented a demonstrated improvement in clinical outcomes, with approximately 0.6 fewer hospital days per patient year and decreased missed dialysis treatments of approximately 0.3 per patient year as compared to a national sample. *See* Mishler R, Sands JJ, Ofsthun NJ, Teng M, Schon D, Lazarus JM. Dedicated outpatient vascular access center decreases hospitalization and missed outpatient dialysis treatments. *Kidney Int.* 2006;69(2):393-398. http://www.ncbi.nlm.nih.gov/pubmed/16408132.

- A recent study comparing ESRD patients of Fresenius dialysis facilities who received vascular access care at a Fresenius Vascular Care affiliated access center to those who did not found that the hemodialysis patients who received care at an access center exhibited 33% lower 6-month mortality. *See* Han H, Chaudhuri S, Usvyat L, et al. Associations between coordinated vascular care visits and decreased rates of hospitalizations and mortality in hemodialysis patients. *J Vasc Access.* 2016;(17):e37-e64. Notably, these observations of improvements in outcomes are similar to the findings reported by other institutions regarding the benefits of freestanding vascular access centers. *See, e.g.* Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial.* 2013;26(5):624-632. doi:10.1111/sdi.12120.

Azura-affiliated vascular access centers have offered this successful care model in North Carolina since approximately 2008, and the proposal here will further improve upon this model. Moving vascular access procedures to a licensed ASC will increase an already high standard of

provider accountability. Conversion to an ASC will also enhance coordination of care. Currently, Petitioners' patients' vascular accesses are surgically created at hospitals – not because the services require a hospital setting or inpatient-level care, but because vascular access creation procedures are generally not reimbursed in the office setting.

A vascular access-focused ASC will allow providers to also perform access-creation procedures, resulting in integrated, coordinated care for dialysis patients. By permitting the same interventional care team to create, follow, repair and maintain the ESRD patient's vascular access in one specialized, regulated outpatient setting, the project will enhance the collaboration between dedicated ESRD providers, resulting in improved clinical outcomes and increased patient satisfaction. ESRD patients can have multiple co-morbidities that further complicate an already complex disease and require visits to multiple providers prescribing multiple care plans. As such, coordination of the ESRD patient's care plans is essential.

Because the proposed operating rooms would exclusively serve ESRD patients, the vascular ASC's providers will offer increased specialization and expertise in episodic vascular access procedures that hospitals cannot match. Forcing these patients into the hospital environment also exposes them to increased risk of infection and other complications and can have adverse implications for post-surgical recovery, potentially resulting in the need for extended and additional services.[4] Allowing for vascular ASCs to provide dialysis patients with the full-spectrum of vascular access care under the auspices of one integrated team of access specialists will optimize care and clinical outcomes for a fragile and complicated patient population.

Licensure of Vascular Access Centers as Ambulatory Surgical Facilities is Necessary to Preserve Access to Care

Azura-affiliated centers in North Carolina had 13,660 Patient visits and performed 11,050 interventional procedures during 2016. The 5,823 patients treated represented 79 of 100 counties, and over a third of North Carolina's total dialysis patient population of 17,387.[5] 74.4% of these patients were Medicare or Medicaid beneficiaries.

But despite the proven track record of purpose-built ESRD vascular access centers, this care model faces extinction as a result of severe cuts to CMS's physician fee schedule reimbursement for ESRD vascular access procedures. Reimbursement for these procedures was cut approximately 30% in the physician office setting effective January 2017.[6] Office-based vascular access centers are staffed and operate very much like a single-specialty ASC, including high levels of specialized staffing, and the drastic reimbursement cuts make it impossible for office-based vascular access centers to maintain sufficient staffing to provide the quality of care that ESRD patients need.

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[4] *See* Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial.* 2013;26(5):624-632. doi:10.1111/sdi.12120.

[5] See July 2017 N.C. Semiannual Dialysis Report, Table A.

[6] See **Exhibit B**, American Society of Diagnostic and Interventional Nephrology (ASDIN) Letter to Andrew Slavitt, August 22, 2016 (commenting on proposed CMS reimbursement cuts to dialysis circuit CPT codes 39601-39609); *see also* 81 Fed. Reg. 80170, 80290-96 (Finalizing 2017 Physician Fee Schedule reimbursement cuts to dialysis circuit CPT code RVUs as proposed).

Consequently, it is no longer viable for physicians to develop or operate office-based vascular access centers, and existing office-based centers will ultimately close. In fact, numerous office-based vascular access centers nationwide have already shut down or are scheduled to close or be sold, less than a year after the cuts took effect, including eleven vascular access centers across the Southern United States, four in California, and three in Ohio and Pennsylvania.

Additionally, numerous office-based vascular access centers that were previously profitable now operate at a loss as a result of the reimbursement cuts. In North Carolina alone, the Practices anticipate substantial capital calls at several centers operated by the Practices and Azura merely to be able to continue operations until the centers can become licensed as or develop ASCs.

If they cannot, the centers cannot continue to operate at a loss indefinitely and will be forced to close, leaving dialysis patients no alternative but to receive surgical interventions in hospitals. This will lead to additional demand on valuable hospital resources, which will of course come with increased costs for patients and the health system overall. In addition, the hospital is a less efficient, less effective environment for these services because hospitals are not designed to respond to the unplanned, though non-emergent nature of hemodialysis access procedures, given the broad scope of care they provide. In a hospital environment, ESRD patients in need of vascular access maintenance do not typically present as emergent cases, which can result in long delays in which they cannot dialyze and their condition deteriorates while waiting to receive necessary maintenance procedures. Specifically, in the experience of Azura-affilated physicians, ESRD patients in the hospital environment often are not seen "urgently" due to competing priorities of the hospital Interventional Radiology (IR) department – the service typically tasked with treating these issues. Urgent ESRD cases are classically placed to the end of the day in hospital IR departments as inpatients so that critically ill patients from the Emergency Department (ED) and Intensive Care Units (ICUs) can be accommodated first, along with previously scheduled IR outpatients. Further delaying care for this population is that many hospital IR departments also require a potassium level be drawn. Furthermore, owing to their competing responsibilities, hospital IR departments often only temporize an urgent or emergent clotted fistula or graft merely by placing a catheter, until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization and the deleterious sequelae of using a catheter for dialysis. Not only can this put the patient's health at risk, it also compounds the already vast investment of time the ESRD patient must commit to life-sustaining dialysis.

Further, traditional non-ESRD focused ASCs suffer from many of the drawbacks of hospitals, and are therefore not a viable alternative for providing vascular access care. Non-vascular ASCs are less accessible to ESRD patients (which are approximately 80% Medicare and/or Medicaid) because ASCs typically rely on a high percentage of higher-reimbursing commercially insured patients and frequently have treatment criteria that rule out this patient population. For example, many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. Critically, traditional ASCs also schedule cases well in advance and cannot accommodate the urgent presentation of dialysis vascular access cases.

Integrating the full spectrum of vascular access services (from surgical access creation through full vascular maintenance) in a more regulated and convenient, Medicare-certified ESRD-focused ASC will preserve access to care in a more cost effective outpatient setting and improve coordination across the continuum of the ESRD patient's care while improving the hemodialysis patient's quality of life.

Vascular Ambulatory Surgery Centers Will Reduce the Cost of ESRD Care

According to the United States Renal Data System, ESRD beneficiaries comprised less than 1% of the Medicare population in 2014 but accounted for an estimated 7.2% of all Medicare fee for service spend, totaling over $32.8 billion.[7] Because most ESRD patients have complex health needs, multiple co-morbidities, and are heavy users of prescription drugs, they often must engage multiple providers, resulting in significantly higher per-patient costs of care across the health care system. Indeed, a typical ESRD patient costs the health care system nearly ten times more than the average Medicare patient.

In the past, providers were able to improve accessibility and quality while lowering overall costs by moving vascular access maintenance procedures from hospital settings to purpose-built physician office settings that functioned much like ASCs. For example, the 2013 Dobson study discussed above determined that the cost of care per patient per month for patients who received services at freestanding vascular access centers was, on average, $584 lower than for other patients.[8]

Now these unlicensed settings are no longer financially viable. Therefore efficient and proactive vascular access treatment– essential to reduce the expense to the health care system generally – requires ESRD focused ASCs. Lacking an ASC environment, vascular access procedures will shift to hospitals, where cost of care and reimbursement far exceed that those in ASCs. See **Exhibit C** (comparison of OPPS and ASC reimbursement for dialysis maintenance procedures). Based on the volume and payor mix of procedures done in Azura-affiliated vascular access centers in North Carolina during 2017 (annualized), doing those procedures in an ASC would save approximately $16.5M in Medicare and Medicaid reimbursement, compared with doing the same procedures in a hospital. See **Exhibit D** (impact analysis of 2017 procedures, annualized, if billed under CMS Hospital Outpatient Prospective Payment System or ASC Payment System). Based on historical growth, Azura expects the ESRD patient population to increase approximately 5% annually, so these savings would show a corresponding increase over time.

By matching specialized resources to ESRD patients' medical needs and eliminating the unnecessary use of inpatient resources, ESRD-focused ASCs would generate additional cost savings – to the patient and the health care system. Studies confirm that access to appropriate outpatient and low-acuity resources can reduce hospital admissions and readmissions and improve patient outcomes, thereby reducing health care expenditures for the patients and the

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[7] United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016 (https://www.usrds.org/2016/view/v2_11.aspx).

[8] *See* Footnote 3, above.

health care system overall.[9] On the other hand, unnecessary reliance on hospital care represents inefficient use of expensive resources and can unnecessarily fragment care and lead to increased potential for hospital readmissions, further driving up costs.

3.a. Adverse effects on population of the requested area likely to ensue if the adjustment is not made:

As noted above, without the requested adjusted need determination, ESRD patients' vascular access care will be forced into hospitals, at a greater cost to the healthcare system but without the specialization or coordination of care that a vascular ASC can provide. Moreover, it would unnecessarily consume limited hospital capacity and resources. Patients needing urgent dialysis procedures (e.g., declotting) who currently have access to office-based vascular access centers will lose access to timely care as those facilities close, and will likely end up in hospital EDs and be admitted while waiting for care (at greater expense, yet increasing the chance of worse outcomes).

Moreover, vascular access creation procedures would remain in the hospital setting, foregoing the advantages in care coordination, improved outcomes and lower cost that a vascular ASC can provide.

3.b. Alternatives to the proposed adjustment that were considered and found not feasible:

1. Status Quo: The status quo is not feasible. As a result of CMS's 30%+ reimbursement cut the remaining office-based vascular access centers are no longer sustainable, and despite numerous closures of vascular access centers in 2017, there is no indication that CMS will increase reimbursement for vascular access procedures under the Physician Fee Schedule. The existing vascular access centers in North Carolina are owned by physician practices with limited resources, which cannot fund the operation of the vascular access centers at a loss indefinitely.

2. Apply to develop an ASC under existing OR need methodology. By statute, an ambulatory surgical facility in North Carolina must have at least one licensed OR,[10] and in 2017, there were no need determinations for additional ORs in any of the counties in which any of the Azura-affiliated vascular access centers currently operate (Mecklenburg, Cabarrus, Caldwell, Wake, Pitt and Craven Counties). Therefore, none of the existing vascular access centers could have been approved to become or to develop a licensed ASC. The proposed 2018 SMFP currently includes need determinations for additional ORs in only two of those counties (Mecklenburg and Wake). Therefore, four existing vascular access centers (in Caldwell, Cabarrus, Craven and Pitt Counties) cannot be approved for a vascular ASC CON in the foreseeable future under the current need methodology. Moreover, there will likely be numerous competitive application in 2018 for the ORs in Mecklenburg and Wake Counties, by hospitals and other surgical providers, and the number of approvable applications may well exceed the number of OR CONs that can be awarded, which could prevent the development of vascular ASCs despite the clear need.

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[9] See Footnote 4, above.

[10] *See* N.C. Gen. Stat. § 131E-176(1b).

4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.

The proposed demonstration project would not result in unnecessary duplication because there are currently no ESRD-focused or vascular ASCs in North Carolina. Moreover, the development of several vascular ASCs would not unnecessarily duplicate hospital surgical capacity because, as noted above in detail:

1. Vascular access maintenance procedures do not require a hospital setting, and are mostly performed in physician offices now. Consequently, shifting maintenance procedures to licensed ASCs will not adversely affect hospital surgical utilization.
2. Dialysis access creation procedures are currently performed as an incidental part of hospitals' broader surgical services, and are secondary to more emergent and clinically intensive surgeries. Therefore, shifting some dialysis access creation procedures to licensed vascular ASCs would improve patient care and outcomes, and reduce the cost to the healthcare system by providing care in a less expensive outpatient setting.

Further, the demonstration project would not unnecessarily duplicate existing ambulatory surgical facilities because:

1. Existing ASCs generally cannot accommodate ESRD patients, who are chronically ill, generally with multiple co-morbidities, and who have frequently missed scheduled dialysis treatments;
2. Existing ASCs' scheduling processes generally cannot accommodate vascular access procedures as they usually present urgently;
3. Non-ESRD focused ASCs lack the specialized clinical staff to provide care with the efficiency and expertise that can be achieved in a vascular ASC.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value.

Safety and Quality: The demonstration project would improve provider accountability by moving vascular access procedures from the office environment to the more highly-regulated ASC environment. Moreover, a lack of licensed vascular ASCs as office-based vascular access centers close will drive ESRD patients to hospitals, which often cannot provide timely care and where the risk of complications and infections is much higher. As noted above, there is extensive evidence that specialized vascular access centers result in better clinical outcomes than other settings.

Access: As noted above, if vascular ASCs cannot be developed, office-based vascular access centers will continue closing, and ESRD patients will lose access the fast, effective, and high-quality care those facilities currently provide. Instead, care will be driven to the hospital setting, where patients usually cannot be seen on an urgent basis.

The creation of licensed vascular ASCs would also improve access to high-quality vascular access creation procedures with better care coordination, better clinical outcomes and lower cost than the hospital setting in which they are currently provided.

The proposed demonstration project would also promote geographic access by including a need determination for vascular ASCs in all six Health Service Areas statewide.

Value: If the status quo persists, existing vascular access centers will continue closing and care will be driven to the more expensive hospital setting, including numerous procedures for indigent patients that are currently provided by vascular access centers free of charge. Also, the inability of hospitals to see patients as quickly as vascular access centers for urgent vascular access maintenance issues will result in patient complications, hospital admissions and expensive care that would be unnecessary if ESRD patients had urgent access to licensed vascular ASCs.

As noted above, CMS reimburses ASCs hundreds or thousands of dollars per procedure less than in the hospital setting, which would save Medicare and Medicaid over $16M in reimbursement in North Carolina alone based on 2017 procedures. Accordingly, licensed vascular access ASCs would save North Carolina's healthcare system tens of millions per year.

ASDIN
AMERICAN SOCIETY OF DIAGNOSTIC AND INTERVENTIONAL NEPHROLOGY

August 22, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1654-P
P O Box 8013
Baltimore, Maryland 21244-8013

RE: File Code-CMS-1654-P; Payment Policies under the Physician Fee Schedule & Other Revisions to Part B For CY 2017; Proposed Rule; (July 15, 2016)

Dear Acting Administrator Slavitt:

The American Society of Diagnostic and Interventional Nephrology (ASDIN) appreciates the opportunity to comment on the 2017 Proposed Physician Fee Schedule. **We specifically wish to address the CMS proposals related to the Dialysis circuit family of CPT codes 369x1, 369x2, 369x3, 369x4, 369x5, 369x6 and 369x7.** CMS did not accept the RUC recommendation regarding the valuation of both physician work and practice expense portions of the codes. We believe that the proposed RVUs are incorrect, and if not adjusted will have severe ramifications for the care of ESRD patients moving forward.

Background

ASDIN is a national medical society with approximately six hundred physician members and one hundred and twenty-five associate members whose focus is the provision of dialysis access care for patients with end-stage renal disease. Our members practice in both hospital and non-hospital settings, performing dialysis access procedures such as angiography, angioplasty, and thrombectomy which assist in the creation, maintenance, and repair of dialysis access. Because of service, quality, and cost considerations, these procedures are often done by our members in specialized vascular centers which are part of the physician office (site of service 11). These highly

focused office-based centers have been demonstrated to provide tremendous value by increasing access to timely procedures, performing continual patient education, coordinating with patients' nephrologist and dialysis facility, and ensuring excellent outcomes. This allows patients to remain on dialysis without disruption due to vascular access complications. Studies have shown that the care patients receive in these centers is of high quality, and has reduced both overall hospitalization and costs to Medicare.

- *Dobson, A. et al Clinical and Economic value of Performing Dialysis Access Procedures in a Freestanding Office-based center as compared with the Hospital Outpatient Department among ESRD beneficiaries. Seminars in Dialysis. 2013.*

We are concerned that the dramatic reductions (see appendix A) in valuation for CPT codes 369x1 through 369x7 in the Physician Fee Schedule (PFS) proposed rule for 2017 would, if finalized, severely threaten the viability of these vascular access centers and lead to both increased costs and disruption of a system of care that has been very positive for patients with kidney disease. Ultimately, this disruption will lead to reduced patient access to timely care and overall reduction in the quality of care received.

Physician Work RVUs

A number of our members participated in the RUC survey of the Dialysis circuit family of codes through their membership in the Renal Physicians Association (RPA). We agree with the RPA comments to the 2017 proposed rule related to the Dialysis Circuit family of codes (369x1 – 369x9). During the survey process, our members recognized a significant problem with the survey that we believe is unique to the Dialysis circuit codes. This survey issue is particularly important because CMS has based its rejection of the RUC recommended physician work RVUs particularly for code 369x1 (the base code in this family) on concern about maintaining appropriate relativity with the Open and Percutaneous Transluminal angioplasty family of codes 372x1 – 372x4. We wish to point out a significant difference between these code families that we believe impacts the work intensity of the Dialysis circuit codes – and makes it appropriate for the dialysis circuit codes to have higher IWPUT as was in the RUC recommended RVUs.

According to CPT, the Dialysis access circuit is defined as originating in the artery adjacent to the arterial anastomosis and including all venous outflow (whether single or multiple veins) to the axillary-subclavian vein junction. We agree with this definition of the dialysis access because each component is integral to having a functional fistula or graft. While several different arteries and veins may be included in this definition, from a functional perspective it is a single "vessel." Hence, it is appropriate to treat the dialysis access as a single vessel for coding purposes and that is how the bundled Dialysis circuit codes (369x1 – 369x6) are built – they include all imaging and intervention within the dialysis access. The dialysis access as defined has a greater propensity for multiple lesions than native vessels in part because of the arteriovenous physiology and in part because it is cannulated with needles on a regular basis. Because of this greater propensity for multiple lesions, it is appropriate to define the access vessel as CPT has done and allow reporting of only a single angioplasty or stent in that entire conduit. This means that there is no code to recognize the work of "additional vessel" angioplasty or stent placement. There is also no code to recognize the additional work of arterial versus venous angioplasty. This is very different than the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). Add-on codes 372x2 and 372x4 describe arterial or venous

angioplasty (respectively) in each additional named vessel. This allows the building of a survey tool with a "typical" vignette with one angioplasty procedure, but appropriately allow reporting the additional work of intervention in a second or third lesion in separate vessels.

However, the survey built on the "typical patient" (51% of the cases) in the Dialysis circuit code family 369x1 – 369x6 is unable to recognize the additional work of additional angioplasty or stent – even though multiple or arterial lesions occur with significant frequency. The higher intensity (IWPUT) of these codes compared to the Open and Percutaneous Angioplasty codes 372x1 and 372x3 reflects the work of treating these additional lesions within the dialysis circuit.

We believe that taking these differences into consideration, the RUC recommended work RVUs for codes 369x1 – 369x6 maintain appropriate relativity between the Dialysis circuit code family (369x1 – 369x6) and the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). We ask that CMS accept the RUC recommended RVUs for codes 369x1, 369x2, 369x3, 369x4, 369x5, and 369x6.

Additionally, since the CMS proposed lower work RVU for 369x7 is based upon comparison to these codes, **we ask that CMS accept the RUC recommended RVUs for 369x7.**

Practice Expense

We believe that the RUC recommended PE inputs for the nine CPT codes in the Dialysis circuit family (369x1 – 369x9) should be accepted and disagree with the refinements proposed by CMS. These are discussed individually in the following paragraphs.

Additional preservice clinical labor time for CPT codes 369x4 – 369x6 (Thrombectomy codes)
These codes describe procedures performed on an urgent basis in a patient with a thrombosed dialysis access. This is different than codes 369x1 – 369x3 which describe procedures performed electively on patients with a dysfunctional dialysis access. The elective procedures are scheduled and planned well in advance of the procedure and performed on days that do not conflict with the patient's dialysis schedule. However, the urgent procedures (369x4 – 369x6) are typically done when a patient presents to their dialysis treatment with a thrombosed access. They are unable to receive dialysis and an urgent call is placed by the dialysis facility to request thrombectomy. These procedures are typically done the same day so that the patient can receive dialysis within 12-24 hours and avoid hospitalization. The urgent nature of the procedure, need for additional preoperative testing because of missed dialysis, and need for arranging unscheduled dialysis treatment requires additional preservice time of the procedural staff. Arranging for an off schedule dialysis treatment is typically the responsibility of the procedural staff after the patient has been assessed in the preoperative area and the plan to restore or obtain dialysis access has been determined.

L037D Clinical labor to prepare and position patient
The RUC proposed additional 3 minutes are reasonable because these cases are done on the upper extremity using portable c-arm fluoroscopy. The additional time includes prepping and positioning the arm, applying appropriate shielding to the patient's torso, positioning the c-arm unit, and then positioning other radiation shielding devices. Prepping the arm can be done in a number of fashions but

typically requires 2 staff members. One staff member dons sterile gloves and holds the patient's arm extended to the side and up off the arm board (many ESRD patients cannot hold their arm in this position for the time required to fully prep). Another staff member then preps the arm and hand including fingers with Chloraprep applicators, applies a sterile glove or towel to cover the hand, and then the patient's arm is lowered into position on the arm board where it can be further draped for the procedure. Each of these activities require more time in the arm case than procedures done in the long plane of the body including the torso and legs. Three minutes is a more accurate reflection of the additional time than CMS's proposed one minute.

Thrombectomy device (Treretola)

A mechanical thrombectomy device (Arrow Trerotola device is most typical, SA015) and a Fogarty thrombectomy balloon (SD032) are both used in a dialysis access thrombectomy because they serve different purposes. The typical thrombosed fistula has an irregular vessel diameter that is filled with thrombus. A thrombectomy device is used to macerate this thrombus so that it can be aspirated or lysed. A pharmacologic agent may also be given to aid in thrombus lysis. This must be done prior to establishing inflow by removing the fibrin plug that forms at the arterial anastomosis. Once thrombus lysis through the body of the access is completed, it is safe to re-establish inflow by passing a Fogarty balloon catheter across the arterial anastomosis, inflating the balloon, and dragging it back into the access through the anastomosis. This maneuver dislodges the fibrin plug, allowing flow into the access. The Fogarty balloon is small and highly compliant allowing it to be pulled through the artery and into the access without damaging the vessels. The thrombectomy device cannot be used safely for this function. This device is larger so risks pushing the fibrin plug into the artery if passed across the arterial anastomosis from the access – risking distal arterial embolization. The device is also much more rigid being made from metal and with irregular shape that risks damaging the endothelium of the artery causing arterial injury. The Arrow Trerotola device packaging specifically warns against using it within the native artery. The Fogarty balloon also is not effective as a thrombus maceration device because of its small size. Both a thrombectomy device and Fogarty balloon are required in the typical fistula thrombectomy case.

Covered stent (Gore Viabahn SD254)

Covered stents are the only stent devices that are FDA approved and supported by evidence from randomized controlled trials for use in dialysis access procedures. They are typically used in recurrent or elastic stenoses in dialysis access – and have become the standard of care for these interventions. They are also used to repair venous rupture caused by balloon angioplasty. This is the reason that a covered stent is included in 369x3 and 369x6. Bare metal stents are still used in central venous angioplasty because of concern that covered stents will occlude the internal jugular vein. That is the reason that the Cordis bare metal stent is included in 369x8.

- *Haskal ZJ, Trerotola S, Dolmatch B, Schuman E, Altman S, Mietling S, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. N Engl J Med. 2010;362(6):494-503.*
- *Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. J Vasc Surg. 2016.*

Hemostatic patch

Two hemostatic patches are required in thrombectomy procedures (369x4 – 369x6) because these procedures require two separate cannulations and sheaths. Opposing sheaths are placed in the access to allow clearing of thrombus in both the arterial and venous portions of the access. The two sheaths also allow imaging and interventions on the entire access. At the end of the case, both sheath sites are removed and covered with a hemostatic patch which aids in preventing bleeding and maintaining sterility.

Chloraprep applicator 26ml

Skin antisepsis prior to percutaneous and open interventions is critical to infection prophylaxis. This is especially important for ESRD patients who have a higher risk of Staphylococcal infections. In the past, povidone iodine has been the most widely used antiseptic for skin cleansing prior to catheter insertion (1). However, studies have shown that preparation of central venous sites with a 2% aqueous chlorhexidine gluconate (in 70% alcohol) is superior for skin site preparation to either 10% povidone-iodine or 70% alcohol alone (2-6). In 2002, the CDC recommended that 2% chlorhexidine be used for skin antisepsis prior to catheter insertion (7). Although not specifically recommended for other interventional procedures, Chloraprep (2% Chlorhexidine gluconate in isopropyl alcohol) has become the typical solution used to prepare the arm and access site for these procedures (369x1 – 369x9). It has demonstrated superiority in preventing procedure related infections due to better antimicrobial properties and more prolonged effect on the skin. Chloraprep is different than Hibiclense solution which is 4% Chlorhexidine (no alcohol). The combination of Chlorhexidine and isopropyl alcohol has greatest efficacy as preoperative skin prep in dialysis catheter and endovascular procedures. Because of this greatest efficacy and CDC recommendations (for catheters), Chloraprep has become standard of care for the Dialysis circuit family of procedures.

1. *Clemence MA, et al. Central venous catheter practices: results of a survey. Am J Infect Control 1995;23:5.*
2. *National Kidney Foundation. Clinical Practice Guidelines for vascular access. Am J Kidney Dis 2006;48(Suppl 1):S176-273.*
3. *O'Grady NP, et al. Guidelines for the prevention of intravascular catheter-related infections. Am J Infec Control. 2011;39(4 Supple 1):S1-34.*
4. *Maki DG, et al. Prospective randomized trial of povodine-iodine, alcohol, and chlorhexidine for prevention of infection associated with central venous and arterial catheters. Lancet. 1991;338(8763):339-43.*
5. *Chaiyakunapruk N, et al. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site are: a meta-analysis. Ann Intern Med. 2002;136(11):792-801.*
6. *Mimoz O, et al. Prospective randomized trial of two antiseptic solutions for prevention of central venous or arterial catheter colonization and infection in intensive care unit patients. Crit Care Med. 1996;24(11):1818-23.*
7. *O'Grady NP, et al. Guidelines for prevention of intravascular catheter related infections. Atlanta, GA, Centers for Disease Control and Prevention. 2002:1.*

Wires

369x1 – 369x3 would typically utilize a micropuncture introducer kit that includes a 0.018" wire, a starter Bentson type 0.035" wire, and a hydrophilic 0.035" wire. Thrombectomy cases (369x4 – 369x6) require an additional 0.035" wire to cross the arterial anastomosis for imaging of the arterial inflow and interventions (commonly occurring) on the arterial side of the access. Once flow is established in the access by means of thrombectomy, a wire and catheter are passed through the access and across the arterial anastomosis so that contrast can be injected directly into the feeding artery. This allows one to

image the peri-arterial dialysis access safely without risking embolization of retained thrombus if an occlusive retrograde contrast injection technique were to be used. Central venous angioplasty cases (369x7 – 369x8) require an additional 260cm wire in order to have adequate length to park the tip in the inferior vena cava. Placing the wire tip in this location is an important safety maneuver to ensure that the wire remains fully across the angioplasty site (in case of rupture) and does not extend into or through the right ventricle causing arrhythmia or bleeding into the pericardium.

Conclusion

Finally, we wish to point out that the cumulative impact of reimbursement reductions for the Dialysis circuit family of codes 369x1 – 369x9, both in terms of physician work and practice expense RVUs, is quite dramatic (see appendix A). If the 2017 proposed work and PE RVUs are implemented many outpatient access centers that focus on providing care for ESRD patients may no longer be able to operate. Having dedicated centers with ability to respond rapidly to immature, dysfunctional, and thrombosed accesses has been critical in improved outcomes seen in the past few years including increased prevalent native arteriovenous fistulas, decreased catheter use, and lower inpatient hospitalization for vascular access complications (USRDS data). Migration of the Dialysis circuit family of codes 369x1 – 369x7 back to the hospital setting will greatly increase cost to the Medicare Program. **We strongly urge CMS to avoid the drastic reimbursement changes that would interrupt the progress made to date and create such challenges for our patients.**

We want to thank CMS for the opportunity to comment on the 2017 Physician Fee Schedule Proposed Rule. We look forward to working with you to ensure the best outcomes for Medicare beneficiaries with ESRD.

Sincerely,

Kenneth Abreo, MD
President
ASDIN

EXHIBIT B

NCN | NORTH CAROLINA NEPHROLOGY, P.A.

919-231-3966

7-31-2017

Christopher Ulrich, MD
Chair, State Health Coordinating Council
Healthcare Planning and Certificate of Need Section
North Carolina Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2714

Re: Letter of Support for Petition for Adjusted Need Determination for the 2018 SMFP - Vascular access ASC Demonstration Project

Dear Dr. Ulrich:

I am a nephrologist in NC Nephrology, PA, a nephrology practice in Raleigh, NC. I appreciate the opportunity to submit this letter in support of the Petition for Adjusted Need Determination submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, North Carolina Nephrology, PA, and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care, requesting the addition of a vascular access ASC demonstration project to the 2018 State Medical Facility Plan ("SMFP").

End Stage Renal Disease (ESRD) patients require chronic life-sustaining dialysis. To receive this therapy, patients require access to the bloodstream via a fistula, graft or hemodialysis catheter or access to the peritoneal cavity via a peritoneal dialysis catheter. These critical accessess are the ESRD patients' "lifeline" for maintaining health. The cost to CMS is disproportionately high for this chronically ill population compared to other medicare recipients; much of this excess cost is due to high hospitalization rates and high cost of the access care. What is clear in the literature over the past 15 years is that managing the care of dialysis access in specialized outpatient centers is less costly to CMS. More importantly it is better care for the ESRD patient as the care is more specialized, timely, and efficient. Hospitalization rates decrease for the dialysis population in areas where their lifeline access care is managed in specialize outpatient centers.

Unfortunately, 2017 Medicare reimbursement cuts have put physician office-based vascular centers at risk, as it is no longer financially feasible for many of these locations to remain in operation. Permitting existing vascular access centers to apply for a certificate of need to operate a single-specialty ASC that provides vascular access services to ESRD patients would ensure the continued availability of necessary services for ESRD patients. All of my interventional colleagues in other states are switching from office based centers to ASC status to maintain financial viability and continue providing critical lifeline access care for the ESRD patients. Certificate of Need laws in those states have not restricted their ability to make this conversion.

I urge the State Health Coordinating Council to approve the Petition for Adjusted Need Determination.

Sincerely,

Jeffrey Hoggard MD, FACP, FASN, FASDIN

August 10, 2018

Christopher Ullrich, M.D., Chairman
North Carolina State Health Coordinating Council
c/o Healthcare Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Novant Health, Inc. Comments Regarding Vascular Access Petition for Demonstration Project in 2018 SMFP

Dear Dr. Ullrich:

Novant Health, Inc. appreciates the opportunity to comment on the petition (the "Petition") submitted on July 26, 2017 by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology Associates (the "Practices"), and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care ("Azura"). Specifically, the Petition proposes an adjusted need determination for a demonstration project to develop two operating rooms in each of the six Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients' vascular accesses. Novant Health has reviewed the Petition, and supports the inclusion of the need determinations described in the Petition, subject to two important caveats:

First, if such need determinations are placed in the 2018 SMFP, the subsequent CON application opportunities must be open to ***all qualified applicants***, including acute care hospitals. These need determinations and CON filing opportunities must not be limited to physician groups (or any other type of applicant, for that matter).

Second, if such need determinations are placed in the 2018 SMFP, all applicants in the subsequent CON reviews should be given equal consideration. In other words, no applicant should have priority consideration in the subsequent CON reviews because it is a physician group, hospital, ASC or some other type of provider.

These modifications are necessary to ensure that the pillars of the SMFP – quality, access and value – are upheld. Several North Carolina hospital systems, including Novant Health, have robust vascular surgery programs and significant experience performing the type of life-saving procedures described in the Petition. To ensure the best possible outcomes for patients, it is critical that all applicants who have the necessary expertise have the chance to apply to meet the need determinations. No applicant – and consequently no patient in need of the services described in the Petition – should be disadvantaged just because the applicant is a hospital.

Further Proposed Modifications to the Petition:

The language of the need determination states that the ASC must be separately licensed, which necessarily excludes hospital outpatient departments ("HOPD") ASCs. Novant Health operates several HOPD ASCs and several separately-licensed ASCs. Both types of facilities play important roles in delivering high quality, cost effective surgical services to thousands of North Carolina residents each year. So as not to exclude potential hospital applicants, Novant Health respectfully suggests that it be left to the applicant to decide which type of facility to propose, and that the SHCC not mandate that the facility be separately licensed. Through the CON review process, the CON Section can decide, among other things, whether the applicant has proposed the least costly or most effective alternative (Criterion (4) of the CON Law) and whether its proposal is comparatively superior to other applicants' proposals in the same review cycle. But the CON process typically does not mandate the specific structure an applicant proposes; rather, it is left to the applicant how best to present its proposal. Novant Health respectfully requests that the SHCC leave it to the applicants to decide how best to present their proposals.

With respect to the chart provided on page 3 of the Petition, it appears that Criteria 1 and 2 are intended to foster physician ownership of the proposed Vascular Access ASCs. Novant Health respectfully suggests that the SHCC should be more concerned about providing access to the services described in the Petition and less concerned about ownership. Hospitals and physician groups routinely compete for CONs, including CONs for ORs. In several cases, the physician groups have been the successful applicants, even without the advantages that Criteria 1 and 2 impliedly confer to physician-only applicants. Further, some hospital applications for ASC CONs – including several ASC CON applications filed by Novant Health and its related entities – have been set up as limited liability companies so that physicians can become owners. Therefore, Novant Health recommends that Criterion 1 and 2 on the chart be deleted.

The applicant in a CON application will have to disclose its ownership, and the CON Section can take that information into account during its review, including in a comparative analysis of the applications. Thus, Criterion 1 (description of percentage ownership interest in the facility by each vascular surgeon and nephrologist) is superfluous. Further, the CON applicant will need to demonstrate the need for its proposed facility and the extent to which key stakeholders (including physicians) have been involved in the planning for the project, and the extent to which they support the project. An "owners only" or "employees only" Vascular Access ASC may have difficulty meeting these requirements, and could be deemed a less effective alternative in a competitive CON review. Thus, Criterion 2 (the proposed facility should provide open access to non-owner and non-employee nephrologists and vascular surgeons) appears to be superfluous. Moreover, a truly "open access" medical staff may conflict with legitimate credentialing processes which may be required by an accreditation body. See Criterion 6. Each facility will need to credential its physicians in accordance with its medical staff bylaws. Again, the CON Section has access to these documents as part of the CON application exhibits, and can decide whether they are consistent with the CON Law, and whether they make an applicant comparatively superior or inferior to another applicant in the same review cycle.

Criterion 5 on the chart on pages 3 and 4 of the Petition would require that "at least 60% of the total number of patients served each year shall be Medicare or Medicaid recipients." Novant Health strongly supports access for medically underserved patients, including Medicare and Medicaid recipients. However, Novant Health urges that the SHCC be cautious about adopting absolute percentages of service to Medicare and Medicaid recipients. The reason is that all providers are operating in a time of tremendous uncertainty. No one knows what the future holds for the Affordable Care Act, Medicare payment changes and Medicaid expansion. A percentage adopted in 2017 with the best of intentions may not be realistic in 2018. Indeed, changes to Medicare reimbursement for in-office vascular access procedures appear to be one of the primary drivers behind this Petition. See, e.g., discussion at page 7 of the Petition.

Due to circumstances that are unforeseen today and beyond any providers' control, providers who are subject to specific percentages may find that they are unable to achieve the mandated percentages. Novant Health is aware that this happened with regard to Triangle Orthopaedic Surgery Center, LLC's Year 3 projections for the single-specialty demonstration project CON that it received as a result of the 2010 need determination. The criteria for the 2010 demonstration projects required that the percentage of the facility's total collected revenue that is attributable to self-pay and Medicaid revenue shall be at least seven percent (the "7% Rule"). See Table 6D from the 2010 SMFP. In its Year 3 report, TOSC noted that as reimbursements from payors improved, the 7% revenue calculation had decreased, even though TOSC remained committed to serving all patients regardless of their ability to pay. See **Exhibit A**.

Again, the CON process takes into account the level of service that applicants provide to the medically underserved. See Criterion (13) of the CON Law. Pursuant to Criterion (13), The CON Section must evaluate applicants' past and projected future performance with respect to service to the medically underserved. In a competitive review, the CON Section can also compare the applicants with respect to their levels of charity care, as well as their levels of service to Medicare and Medicaid recipients. Thus, the current process effectively addresses the concern raised by Criterion 5 of the proposed need determination. Novant Health respectfully suggests that Criterion 5 be eliminated as part of the proposed need determination.

In sum, Novant Health supports the Petition, provided that the need determination does not exclude any qualified applicant, including acute care hospitals, from applying to meet the need determination and provided that no applicant is given priority based on its status as a hospital, physician group, ASC, etc. Having a level playing field for this demonstration project is essential to ensure quality, access and value. These comments also provide specific suggestions on changes to the criteria proposed on pages 3 and 4 of the Petition.

Novant Health appreciates the opportunity to have its views considered by the SHCC.

Sincerely,

John W. Foster Mann, MD
Novant Health Surgical Service Line Leader

CC: Barbara L. Freedy, Director, Certificate of Need
Novant Health, Inc.
blfreedy@novanthealth.org

File: Novant Support for Vascular Access petition.08.10.17.docx

DELIVERED VIA EMAIL AUGUST 10, 2017

August 7, 2017

Christopher Ullrich, M.D., SHCC Chair
Sandra Greene, Dr.P.H., Acute Care Service Committee Chair
North Carolina State Health Coordinating Council and Acute Care Service Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Surgical Care Affiliates, Inc. Comments Regarding the Petition for an Adjusted Need Determination for 2018 State Medical Facilities Plan Demonstration Project – Vascular Access Ambulatory Surgery Center for ESRD Patients

Dear Dr. Ullrich and Dr. Greene,

Surgical Care Affiliates, Inc. (SCA) appreciates the opportunity to comment on the Petition submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, North Carolina Nephrology, PA, and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (the Petitioner) for an adjusted need determination for a demonstration project to develop two operating rooms in each of the six Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients' vascular accesses.

During your review, I urge you to consider the unwarranted and unsupported need for operating rooms dedicated to vascular access procedures currently served in physician office settings.

Sincerely,

Cory Hess
Vice President, Operations
Surgical Care Affiliates, Inc.

Attachment(s)

Request to Deny Petition for an Adjusted Need Determination for *2018 State Medical Facilities Plan* Demonstration Project – Vascular Access Ambulatory Surgery Center for ESRD Patients

Surgical Care Affiliates (SCA) is urging the State Health Coordinating Council (SHCC) to deny this Petition. The petition provides no evidence to support the need for any single specialty freestanding ambulatory surgical centers (ASC) dedicated to vascular access in North Carolina. Moreover, the petition has multiple other unsupported claims.

No Evidence to Support Need for Demonstration Project

The Petition fails to provide any clinical evidence to support the claim that vascular access procedures currently performed in office-based settings, now require a licensed operating room (OR). In fact, The Petition points to the success and efficiency of office-based vascular access centers serving end-stage renal disease (ESRD) patients:

> *"...since the early 2000s, dedicated, physician office-based vascular access centers have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within hours." (p5)*

As stated by the petitioner, the care required to maintain a patient's existing vascular access can be performed in a physician's office.

The only discussion provided to support the Petition's request is the decline in Medicare reimbursement payments for office-based vascular access procedures. Any procedure performed in a freestanding ASC is reimbursed a "facility fee." The Petition is effectively asking for an offsetting increase in reimbursement for Fresenius Vascular Care, Inc and four nephrology practices. The Petition provides no detail on the financial impact of the recent reduction in Medicare payment. It provides no reasons why the petitioners could not apply for operating rooms already included in the Proposed 2018 SMFP. The Petition alludes to four existing centers and indicates that approval would "also enable the development of new centers in areas not yet served." (p5) It provides no data to support the need for those new centers or to describe where they would be located.

The Petition does not explain why North Carolina needs two operating rooms in each of Health Service Area.

Misleading Claims

In addition to providing no evidence that vascular access procedures currently performed in office-based procedure rooms, now require a licensed OR, the Petitioner also makes several speculative assertions.

The Petition claims vascular access office-based procedure rooms are no longer sustainable:

> *"...office-based vascular access centers, and existing office-based centers will ultimately close." (p8)*

However, the Petition provides no evidence that a decline in Medicare reimbursement is the direct cause of the closure of vascular access centers in other states. The Petitioner implies that insurance companies will support the relocation of vascular access procedures currently performed in office-based procedure rooms to an ASC OR and would pay the facility fee. The Petition provides no supporting documentation. The Petitioner includes no information regarding how insurance companies would cover these procedures in an ASC OR.

The Petitioner also suggests that existing ASCs cannot accommodate these procedures:

> *"Further, traditional non-ESRD focused ASCs suffer from many of the drawbacks of hospitals, and are therefore not a viable alternative for providing vascular access care. Non-vascular ASCs are less accessible to ESRD patients (which are approximately 80% Medicare and/or Medicaid) because ASCs typically rely on a high percentage of higher-reimbursing commercially insured patients and frequently have treatment criteria that rule out this patient population. For example, many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. Critically, traditional ASCs also schedule cases well in advance and cannot accommodate the urgent presentation of dialysis vascular access cases." (p8)*

This is completely unfounded. As mentioned by the Petitioner, a majority of ESRD patients are Medicare beneficiaries which the Petition implies, reimburses enough for these cases to be attractive to an ASC. Ambulatory surgery centers do accommodate work-in cases. SCA facilities regularly accommodate add-on cases. In certain situations, if a vascular ESRD surgeon performs procedures regularly, SCA would dedicate a procedure room to vascular access procedures. Moreover, the Petitioner claims non-ESRD focused ASCs are less accessible to ESRD patients, yet it provides no evidence; no documentation showing refusal of access was included with the Petition.

The petition is confusing:

> *"...Petitioners' patients' vascular accesses are surgically created at hospitals – not because the services require a hospital setting or inpatient-level care, but because vascular access creation procedures are generally not reimbursed in the office setting." (p7)*

Overall, the Petition makes a poor distinction between the creation of the access and the maintenance and repair of the access. On one hand, they say creation only happens in hospitals, on the other, is says is can be performed in ASC. The Petition does not address why the Petition's affiliates are not currently performing vascular access creation procedures in ASCs.

By discounting freestanding ASCs as a viable option for these patients, the Petitioner is completely disregarding existing ASCs with available capacity. SCA has ASCs in HSA IV, V, and VI, all of which have capacity for accommodating vascular access procedures in addition to their current caseloads. The Petition also fails to take into account the 30 ORs in the 2018 SMFP, which will add capacity in HSA I, II,

and III. Between SCA facilities, and the need for more ORs in the 2018 Plan, there is ample capacity for these procedures, which permits an alternative other than the hospital.

The creation of a vascular access by a vascular end-stage renal disease (ESRD) specialist requires common surgical center equipment (i.e., x-ray and fluoroscopy C-arms) and trained physicians/staff, but it rarely requires a licensed operating room. General anesthesia is often avoided during the creation of a patient's vascular access due to the prevalence of comorbid conditions within the ESRD patient population.[1] A patient with multiple co-morbidities requiring general anesthesia is best served in a hospital setting. As a result, local anesthesia is commonly used during vascular access.[2] A procedure room outfitted for vascular access procedures can support a vascular access procedure that requires local anesthesia. The Petition fails to make a persuasive argument to justify up to 12 new ORs in NC. Thus, the need for specialized ESRD ASCs across the state is unjustified.

[1] http://jasn.asnjournals.org/content/14/12/3270.full.pdf+html
[2] https://academic.oup.com/bjaed/article/14/3/119/341072/Anaesthesia-for-vascular-surgery-of-the-upper-limb

Letters in Support of the Petition for Adjusted Need Determination for Demonstration Project - Vascular Access Ambulatory Surgery Centers for ESRD Patients

	NAME	PRACTICE	CITY	SPECIALTY
1	Andrew O'Connor, DO	Metrolina Nephrology Associates	Monroe	Nephrologist
2	Anjali Singla, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
3	Benjamin Hippen, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
4	Charles Stoddard III, MD	Metrolina Nephrology Associates	Concord	Nephrologist
5	Chris Fotiadis, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
6	Christopher Buehrig, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
7	Daniel Tierney, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
8	Donald Berling, M.D.	Metrolina Nephrology Associates	Charlotte	Nephrologist
9	Ernest F. Johnson, III, MD	Metrolina Nephrology Associates	Salisbury	Nephrologist
10	George Hart, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
11	Gregory Merten, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
12	Jeffery Nielsen, MD	Metrolina Nephrology Associates	Morrisville	Nephrologist
13	Joel Bruce, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
14	John Dashiell, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
15	John S. Gerig, MD	Metrolina Nephrology Associates	Concord	Nephrologist
16	Jonathan Planer, MD	Metrolina Nephrology Associates	Gastonia	Nephrologist
17	Kimberly Yates, MD	Metrolina Nephrology Associates	Huntersville	Nephrologist
18	Matthew Elliott, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist

	NAME	PRACTICE	CITY	SPECIALTY
19	Maurice Gene Radford, Jr., MD	Metrolina Nephrology Associates	Gastonia	Nephrologist
20	Mehul Patel, MD	Metrolina Nephrology Associates	Concord	Nephrologist
21	Michael Etomi, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
22	Nancy Gritter, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
23	Nathan Woolwine, MD	Metrolina Nephrology Associates	Salisbury	Nephrologist
24	Paul Blake, DO	Metrolina Nephrology Associates	Charlotte	Nephrologist
25	Paul Cheifetz, MD	Metrolina Nephrology Associates	Gastonia	Nephrologist
26	Peale Chuang, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
27	Steve Haigler, MD	Metrolina Nephrology Associates	Monroe	Nephrologist
28	Suzanne Katsanos, MD	Metrolina Nephrology Associates	Gastonia	Nephrologist
29	Thomas R. Smarz, Jr., MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
30	Todd Griffith, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
31	Verachai Lohavichan, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
32	Vivek Sanghani, MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
33	Douglas Nigbor, MD	Metrolina Nephrology Associates	Gastonia	Nephrologist
34	Edward Carl Fisher, Jr., MD	Metrolina Nephrology Associates	Charlotte	Nephrologist
35	Kristel J. McLawhorn, MD	Eastern Nephrology Associates	Greenville	Nephrologist
36	M. Carney Taylor, Jr., MD	Eastern Nephrology Associates	Greenville	Nephrologist
37	Manuel Montero, MD	Eastern Nephrology Associates	New Bern	Nephrologist

	NAME	PRACTICE	CITY	SPECIALTY
38	Maxwell E. Fisher, MD	Eastern Nephrology Associates	Greenville	Nephrologist
39	Graham V. Byrum, Jr, MD	Eastern Nephrology Associates	Greenville	Nephrologist
40	J. Clint Parker, MD	Eastern Nephrology Associates	Greenville	Interventional Nephrologist
41	Nathan Saucier, MD	Eastern Nephrology Associates	New Bern	Interventional Nephrologist
42	Nauman Shahid, MD	Eastern Nephrology Associates	Greenville	Nephrologist
43	Nawaf G. Atassi, MD	Eastern Nephrology Associates	Kinston	Nephrologist
44	Ram Sapsetty, MD	Eastern Nephrology Associates	Kinston	Nephrologist
45	Rekha John, MD	Eastern Nephrology Associates	Kinston	Nephrologist
46	Richard D. Blair, MD	Eastern Nephrology Associates	New Bern	Interventional Nephrologist
47	Scott A. Kendrick, MD	Eastern Nephrology Associates	Greenville	Nephrologist
48	Stuart Jennings, MD	Eastern Nephrology Associates	New Bern	Nephrologist
49	Thomas E. Burkart, MD	Eastern Nephrology Associates	New Bern	Nephrologist
50	Vernon Chiu, MD	Eastern Nephrology Associates	Kinston	Nephrologist
51	Walter J. Newman, MD	Eastern Nephrology Associates	New Bern/Moorehead City Area	Nephrologist
52	William T. Kendrick, MD	Eastern Nephrology Associates	Greenville	Nephrologist
53	Ajay Shreenath, MD	Carolina Nephrology, P.A.		Nephrologist
54	K. V. George Thomas, MD	Southeastern Nephrology Associates	Jacksonville	Nephrologist
55	Richard D. Blair, MD	Carolina Kidney Care, PA	Fayetteville	Nephrologist

	NAME	PRACTICE	CITY	SPECIALTY
56	Karn Gupta, MD	North Carolina Nephrology	Raleigh	Interventional Nephrologist
57	Milagros Cailing, MD	Coastal Nephrology, P.O.	Jacksonville	Nephrologist
58	Nirav M. Jasani, MD	Will Bynum MD PA	Wilson	Nephrologist
59	Tariq Abo-Kamil, MD	DLP Maria Parham Physician Practices LLC	Henderson	Nephrologist
60	Byron C. Abels, MD	Regional Vascular Associates	Cary	Vascular Surgeon
61	Anwar D. Al-Haidary, MD	Wilson Nephrology – Internal Medicine, PA	Wilson	Nephrologist

EXHIBIT C

Acute Care Services Committee
Agency Report
Adjusted Need Petition for
Demonstration Project for Vascular Access Ambulatory Surgery Centers for End-Stage Renal Disease Patients in the 2018 State Medical Facilities Plan

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Petitioners:
American Access Care of NC, PLLC
Eastern Nephrology Associates, PLLC
Metrolina Nephrology Associates, PA
North Carolina Nephrology, PA
Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

Contact:
Murat Sor, MD
Chief Medical Officer
Azura Vascular Care
52 E. Swedesford Rd., Suite 110
Malvern, PA 19355
(610) 644-8900
Marc Hewitt, Smith Moore Leatherwood
Marc.Hewitt@smithmoorelaw.com

Request:
Azura Vascular Care and four medical practices, listed above, request an "...adjusted need determination for a demonstration project to develop two operating rooms in each of the six Health Services Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary..." for end-stage renal disease (ESRD) patients. A vascular access is necessary to enable the dialysis machine to access the patient's blood for filtration and return to the patient.

Background Information:
Chapter Two of the *North Carolina Proposed 2018 State Medical Facilities Plan (SMFP)* provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions requesting adjustments to policies and methodologies in the spring. The planning process and time allow for submission of petitions requesting adjusted need determinations in the summer. It should be noted that any person might

submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The new need methodology consists of several steps to determine the number of ORs needed in each OR service area. The methodology projects the number of surgical hours by first multiplying the average case times reported by each facility by the hours for inpatient and ambulatory cases for the previous year (data year). This result is then multiplied by the projected population change between the data year and four years beyond the data year (target year). The number of operating rooms required by the target year is the result of dividing the projected number of surgical hours for the target year by the number of hours per OR per year for each facility based on assumptions used in the SMFP, while accounting for outliers. The final step calculates the number of additional ORs needed by subtracting the projected total number of required ORs from the current OR inventory for each health system in the service area. Deficits for all health systems are summed to obtain the need for ORs in the service area.

Vascular access centers provide the surgical creation, management and maintenance of ESRD patients' vascular accesses. They may also provide other vascular and interventional radiological services not related to ESRD. There are three types of vascular access for ESRD – catheter, arteriovenous (AV) graft, and AV fistula. The National Kidney Foundation recommends the use of AV fistulas whenever feasible because they are associated with the lowest rate of complications.[1]

The impetus for the petition is that the Centers for Medicare and Medicaid Services (CMS) instituted a bundled payments structure for vascular access procedures on January 1, 2017. The Society for Vascular Surgery claims that a fee-for-service system produces an inherent incentive for physicians to treat immediate problems only. The purpose of bundling is to "target the highest quality vascular access method for a given patient" and then to "set up a bundled/global payment that incorporates placement of the vascular access as well a maintenance of this access over some defined period of time."[2] The Petitioner asserts that because of this change, "existing physician office-based vascular access centers will no longer be sustainable if they cannot become licensed ambulatory surgical facilities and will close, forcing ESRD patients into hospitals" (page 1).

Analysis/Implications:

Impact of New Regulations on Vascular Access Centers

Medicare is the primary or secondary coverage for approximately 84% of ESRD patients.[3] CMS implemented bundled payments for dialysis services and supplies in 2011 to help control costs.[4] The specific goal of the bundled payment structure for vascular access is to have a zero percent impact on nephrology reimbursement overall.[5]

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[1] http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm

[2] https://vascular.org/news-advocacy/svs-medicare-physician-payment-plan-2013

[3] United States Renal Data System. *2016 Annual Data Report.* Data as of 2014, includes patients receiving dialysis as well as those who have had kidney transplants. https://www.usrds.org/2016/view/Default.aspx

[4] https://www.usrds.org/2016/view/v2_11.aspx

[5] Riley, James B. & Greis, Jason S. (2016). Practical Considerations for Medical Practices Considering Converting their Vascular Access Centers into Medicare-Certified Ambulatory Surgery Centers. Chicago: McGuireWoods LLP.

Several sources have estimated that the potential impact of the new regulations will decrease revenue by an average of 30-40% for vascular access procedures for ESRD patients, when performed in a physician's office.[6] Moving vascular access procedures from a procedure room in a medical practice to a hospital setting will undoubtedly incur significant costs to Medicare. Doing so may also put patients at greater risk of health care-associated infection. Therefore, development non-hospital-affiliated ORs is one solution being sought.

The CMS bundled payment structure is not unique to vascular access centers. While physician practices will undoubtedly need to make adjustments, converting vascular access centers to ambulatory surgical facilities (ASF) represents only one option. For example, many vascular access centers perform procedures unrelated to ESRD. An ASF dedicated to the ESRD niche may not be the most reasonable medical or business option for these centers.

Potential Need for Dedicated Vascular Access ASF

Apart from any motivations for a demonstration project, it is necessary to consider whether the proposed ORs can be financially sustainable. The Petitioner discusses two types of care to be provided in the proposed facilities: initial vascular access and vascular access intervention. According to the Petitioner, it is standard practice to perform the initial vascular access in a hospital, because the procedure is not reimbursed in a doctor's office. The most common type of procedure in the proposed ORs would be vascular access repair. When intervention is needed, it often must occur within a day or two after an access failure or after discovery of an infection or other issue.

The Petition (page 5) notes that "the average dialysis patient experiences 2.2 to 2.5 access interventions per year." The Petition (page 7) states that Azura-affiliated practices performed 11,050 procedures on 5,823 patients in North Carolina in 2016. This represents an average of 1.9 procedures per patient. It is unknown whether 5,823 represents the total number of patients associated with these practices. While an average of two procedures per patient were performed on those patients who needed intervention, it is not possible to estimate the proportion of total ESRD patients who need intervention in an average year. Based on other information in the Petition, failure rates appear to be considerably less than 10% annually.

The Petition further states that Azura practices cover 79 of the 100 counties in the state. If coverage of 79 counties indicates inclusion of roughly 79% of the total ESRD patients, then it is reasonable to increase the 5,823 by 20% to estimate that a total of about 7,000 patients would need intervention annually, for a total of approximately 14,500 procedures (at two per patient). The Petition provides no information on the average length of vascular access procedures performed in Azura-affiliated practices. Upon initial examination, the number of prospective patients may not be sufficient to support 12 new ambulatory surgical ORs dedicated specifically to the needs of ESRD patients. The July 1, 2017 North Carolina Semiannual Dialysis Report shows that dialysis centers served 17,387 dialysis patients statewide as of December 31, 2016. An OR in an ambulatory surgical facility requires 1,312.5 surgical hours per year for full utilization. Only if most of the 17,387 ESRD patients were to require vascular access repair or replacement annually

[6] Neumann, Mark E. (2016, September 29). *Nephrology: News & Issues.* Proposed bundling in Medicare Fee Schedule could cut interventional access revenue up to 40%.

could 12 ORs be supported, assuming the procedure lasted an average of 60 minutes. The Agency did not have an enough data to answer some of the most important questions in analyzing this request. These include:

- What is the breakdown of vascular access type among ESRD patients in North Carolina?
- What proportion of ESRD patients in North Carolina are likely to require vascular access intervention in any given year?
- Among patients who require intervention, on average, how many times a year is intervention required?
- What are the most common types of interventions, and in what proportions?
- What is the average case time for interventions currently conducted in procedure rooms?
- What potential proportion of new ESRD patients may be suitable to have initial vascular access performed in an ASF?

Agency Recommendation:
The Agency supports the new methodology for OR need determination. However, before recommending demonstration projects, the Acute Care Services Committee and the SHCC carefully examine the pertinent issues and provide opportunities for input from subject area experts and the public.

Historically, the SHCC has taken one full cycle for consideration of complex planning requests. For example, before approving the Single Specialty Ambulatory Surgical Facility Demonstration Project, the SHCC established a workgroup that began consideration of the demonstration in November of 2008. The project was approved for implementation in the 2010 SMFP. More recently, consideration of the Dental Ambulatory Surgical Facility Demonstration Project began in March 2016, with implementation in the 2017 SMFP.

Sufficient time does not exist for proper consideration of the proposed demonstration project for the 2018 SMFP. With these considerations in mind and given available information and comments submitted by the August 10, 2017 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition.

EXHIBIT D

Petition for Change in Need Methodology for the 2019 State Medical Facilities Plan
Or, in the Alternative, an Adjusted Need Determination for a Demonstration Project –
Vascular Access Ambulatory Surgery Centers for ESRD Patients

March 7, 2018

This Petition is jointly submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology, PA (the Practices), and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (Azura), which operate several outpatient vascular access centers in North Carolina specializing in the management and maintenance of End Stage Renal Disease (ESRD) patients' vascular accesses, which are necessary for life-sustaining hemodialysis treatments.

Petition for Change in Need Methodology Pertaining to Operating Rooms

The Practices and Azura propose a change in the need methodology pertaining to the development of operating rooms. Specifically, the Practices and Azura propose that dedicated vascular access operating rooms located in single-specialty ambulatory surgical facilities be excluded from the SMFP's annual operating room inventory. As a result, applicants could submit a CON application at any time, regardless of the SMFP's operating room need inventory, to develop dedicated vascular access operating rooms. Applicants would still be required to demonstrate need and comply with the CON standards applicable to operating rooms. Dedicated vascular access operating rooms would thus be treated similarly to dedicated c-section operating rooms, which require CON approval to develop but which are not included in the operating room inventory and can be developed after a demonstration of need, regardless of the operating room need determination in the SMFP.

As discussed in detail herein, physicians have long operated unlicensed vascular access centers ("VACs") in the physician office setting. These VACs have enabled individuals with ESRD to receive safe, prompt care to manage the vascular access sites used to receive life-sustaining kidney dialysis treatments and to avoid costly emergency department visits. Due to recent Medicare reimbursement changes, however, it is no longer financially feasible for many VACs to continue operation. Without the ability to convert these existing, unlicensed VACs into single-specialty ambulatory surgical facilities, many physicians have been or will be forced to stop offering this valuable service, forcing ESRD patients into hospital emergency rooms and jeopardizing their health and safety. Unfortunately, under the current methodology applied to operating rooms, little opportunity exists to convert these existing, unlicensed rooms to licensed operating rooms.

Petition for Adjusted Need Determination – Single-Specialty Vascular Access ASC

In the alternative, the Practices and Azura propose an adjusted need determination for a demonstration project to develop two (2) operating rooms in each of the six (6) Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients' vascular accesses. These facilities

will improve access to life-sustaining dialysis care, the quality of vascular access care for ESRD patients, and clinical outcomes for these patients.

Background

Kidney disease statistics for the United States indicate that between 8-10% of adults have some level of chronic kidney disease (CKD)[1], and individuals with complete kidney failure – i.e., End Stage Renal Disease (ESRD) – must have either dialysis or a kidney transplant to survive. As of June 30, 2017, 17,789 North Carolina residents were undergoing dialysis for ESRD.[2] These patients must undergo routine, ongoing hemodialysis, in which their blood is filtered through a machine that removes waste products from the blood, and which requires vascular access. Vascular access, including an arteriovenous (AV) fistula or graft, enables a dialysis machine to access a patient's blood and facilitate the removal and filtration of the blood before it is returned to the patient. While indispensable to hemodialysis treatment, vascular accesses have very high dysfunction rates, with patients being susceptible to clotting, infection, and venous injury. Therefore, dialysis access management and treatment of vascular access complications is critical to an ESRD patient's plan of care. Absent a functioning vascular access, ESRD patients cannot receive dialysis and are at risk of hospitalization, serious complications, and death.

Because of recent regulatory and reimbursement changes, many physicians will not be able to continue to provide this valuable service in their existing, physician office-based vascular access centers if they cannot become licensed ambulatory surgical facilities. Physicians will cease offering these services in the VAC setting, forcing ESRD patients into hospitals. Providing vascular access services in the hospital setting will result in unnecessary use of inpatient resources, unnecessary hospital admissions and increased costs to patients and the health care system, unnecessary delays in a patient's ability to dialyze, exposure to infection risk associated with an inpatient setting, and fragmentation of care. Consequently, providing vascular access services in hospitals will result in much greater expense, and with worse patient outcomes.

1. Name, address, email address and phone number of petitioners:

American Access Care of NC, PLLC
American Access Care of NC is an interventional radiology and vascular surgery practice located in Cary.

Eastern Nephrology Associates, PLLC
Eastern Nephrology Associates is a 20-physician nephrology practice headquartered in Greenville and New Bern, serving eastern North Carolina since 1975.

Metrolina Nephrology Associates, PA
Metrolina Nephrology Associates is a 34-physician nephrology practice with offices in Charlotte, Concord, Gastonia, Huntersville, Monroe, Mooresville, and Salisbury, serving the Metrolina area for over 40 years.

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[1] World Kidney Day: Chronic Kidney Disease. http://www.worldkidneyday.org/faqs/chronic-kidney-disease/.
[2] January 2018 N.C. Semiannual Dialysis Report, Table A.

North Carolina Nephrology, PA
North Carolina Nephrology (formerly Capital Nephrology Associates and Wake Nephrology Associates) is a 20-physician nephrology practice with offices in Raleigh, Cary, Fuquay-Varina, Zebulon, Smithfield, Louisburg, and Dunn, serving Raleigh and the surrounding counties.

Fresenius Vascular Care, Inc.
Azura Vascular Care is the trade name of Fresenius Vascular Care, Inc., a national network of outpatient vascular care and ambulatory surgery centers that specialize in minimally invasive techniques to treat and manage vascular conditions. Azura-affiliated vascular access centers currently operate in Raleigh, Cary, Greenville, New Bern, Charlotte, and Concord NC.

Address/Email Address/Phone Number of Petitioners:
Azura Vascular Care
Attn: Murat Sor, MD
Chief Medical Officer
murat.sor@azuracare.com
52 East Swedesford Road, Suite 110
Malvern, PA 19355
610-644-8900

2. Statement of requested adjustment, citing provision in proposed SMFP for which adjustment is proposed.

Change in Need Methodology

The Practices and Azura request a change to the Operating Room Need Methodology in Chapter 6 of the SMFP to exclude from the operating room inventory and the need methodology dedicated vascular access operating rooms. This change would read as follows:

Summary of Operating Room Inventory and Utilization
[...] In the fall of 2018, the combined inventory of operating rooms in hospitals and ambulatory surgical facilities in North Carolina, excluding Dedicated Vascular Access Operating Rooms located in single-specialty vascular access ambulatory surgical facilities, consisted of _____. [...]

Changes from the Previous Plan

- Dedicated Vascular Access Operating Rooms located in single-specialty vascular access ambulatory surgical facilities are excluded from the inventory and the utilization rate used to project operating room need.

Assumptions of the Methodology
For purposes of the operating room methodology, a "Dedicated Vascular Access Operating Room" means an operating room located in a licensed, CON-approved ambulatory surgical facility that is used exclusively to provide vascular access creation and maintenance procedures for patients with advanced chronic kidney disease (CKD) or end-stage renal disease (ESRD) to permit these patients to undergo kidney dialysis treatments. [...]

Methodology for Projecting Operating Room Need
Step 2 – Inventory of Operating Rooms

b. For each facility:
   (1) [...]
   (2) [...]
   (3) Exclude the number of Dedicated Vascular Access Operating Rooms located in licensed single-specialty vascular access ambulatory surgical facilities (*Column __*)
   (4) List the number of operating rooms (*Column I*) and C-Section operating rooms...

NOTE: "Dedicated C-Section Operating Rooms" and "Dedicated Vascular Access Operating Rooms" and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a "Dedicated C-Section Operating Room," or applicants proposing to develop or add a new operating room to a single-specialty vascular access ambulatory surgical facility for use as a "Dedicated Vascular Access Operating Room" shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan. There are no other operating room exclusions for which this protocol is applicable.

[...]

A "Dedicated Vascular Access Operating Room" shall only be used to perform vascular access creation and maintenance procedures on advanced CKD or ESRD patients.

Adjusted Need Determination – Demonstration Project

In the alternative, the Practices and Azura request an adjusted need determination for the development of two (2) dedicated vascular access operating rooms in each Health Service Area in the State, exclusively to provide vascular access procedures for advanced chronic kidney disease (CKD) or end stage renal disease (ESRD) patients in separately licensed ambulatory surgical facilities. This change would constitute a change to Chapter 6 of the SMFP, and would read as follows:

Table 6___: Renal Single Specialty Ambulatory Surgical Facility Demonstration Project

Operating Room Service Area	Operating Room Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
HSA I	**2***		
HSA II	**2***		
HSA III	**2***		
HSA IV	**2***		
HSA V	**2***		
HSA VI	**2***		

* Need determination is pursuant to the Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project.

Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project
In response to a petition from several physician practices and Azura Vascular Care, an adjusted need determination for Vascular Access Single Specialty Ambulatory Surgical Demonstration Projects (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state serves the access and value Basic Principles by avoiding a concentration of Vascular Access Ambulatory Surgical Centers in one geographic area. There is a need determination for up to two operating rooms in each of the six Health Service Areas statewide, which operating rooms must be located in separately licensed vascular access single specialty ambulatory surgical facilities.

Applicant(s) shall demonstrate in the certificate of need application that the proposal will meet each criterion set forth below.

	Criterion	Basic Principle and Rationale
1	The application shall contain a description of the percentage ownership interest in the facility by each vascular surgeon and nephrologist.	Value – Implementing the innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
2	The proposed facility shall provide open access to non-owner and non-employee nephrologists and vascular surgeons.	Access – Services will be accessible to a greater number of ESRD patients if the facility has an open access policy for nephrologists and vascular surgeons.
3	The operating rooms shall provide only vascular access creation and management procedures for ESRD patients and advanced CKD patients.	Value – Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
4	The proposed facility shall be certified by the Centers for Medicare and Medicaid Services (CMS), and shall commit to continued compliance with CMS conditions of participation.	Access – Requiring services to low income and medically underserved patients promotes equitable access to the services provided by the demonstration project facilities.
5	The proposed operating rooms shall provide care to underserved patients. At least 60% of the total number of patients served each year shall be Medicare or Medicaid recipients.[3]	Access – Requiring Service to Medicare patients promotes equitable access to the services provided by the demonstration project facilities.
6	The proposed facility shall obtain accreditation after licensure by the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or the Joint Commission (TJC), and shall commit to continued compliance with	Quality – Adherence to certification processes ensures that the facility is committed to meeting the generally accepted industry standards for quality and safety for their patients.

[3] By law, Medicare is the designated ESRD insurance program. As a result, ESRD patients of any age qualify for Medicare if they are eligible for Social Security disability, and Medicare remains the primary insurer for most ESRD patients. *See* Social Security Administration Program Operations Manual System, § DI 45001.001, "End Stage Renal Disease (ESRD) Entitlement Provisions," *available at* http://policy.ssa.gov/poms.nsf/lnx/0445001001

	their respective standards.	
7	Health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital and medical staff bylaws, are required to establish or maintain hospital staff privileges with at least one hospital with which the proposed facility has a transfer agreement in place.	Quality and Access- Encouraging health care professionals to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps ensure the continued viability of community based hospital resources.
8	The proposed operating rooms shall meet all reporting, monitoring and evaluation requirements of the demonstration project set forth by the Agency.	Safety and Quality, Access, Value - Timely monitoring enables the Agency to determine whether proposed projects are meeting criteria and to take corrective action if approved applicants fail to meet criteria.
9	For each of the first three full federal fiscal years of operation, the applicant(s) shall provide the projected number of procedures in each proposed operating room for the following payor types: (i) charity care/self-pay; (ii) Medicare; (iii) Medicaid; (iv) TRICARE; (v) private insurance; and (vi) payment from other sources.	Access - Requiring service to a wide range of patients promotes equitable access to the services provided by the demonstration project facilities.
10	The performance standards in 10A NCAC 14C.2103 would apply.	Value - Performing at least a minimum number of outpatient procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.

To ensure that the demonstration project facilities meet all three Basic Principles, each selected site shall be required to provide annual reports to the Agency showing compliance with the criteria in Table ___ of the 2019 State Medical Facilities Plan. The Agency shall specify the report components and format. The Agency will produce an annual summary of each facility's annual report, and will evaluate the demonstration project after it has been in operation for three full federal fiscal years. Depending on the results as presented by the Agency, the State Health Coordinating Council shall consider whether to permit expansion beyond the original demonstration project sites.

3. Reasons for the Proposed Adjustment:

A change to the operating room need methodology or, in the alternative, an adjusted need determination, should be included in the 2019 SMFP in order to preserve access to life-saving, high-quality care historically provided by physician office-based vascular access centers that provide dialysis access maintenance services. Allowing for existing vascular access centers to become licensed ASCs will enable the Practices and other providers to continue serving the vulnerable ESRD patient population. A change to the operating room need methodology or a demonstration project would also enable the development of new centers in areas not yet served. Therefore, allowing this petition will improve access to and quality of care, reduce the cost of care, and critically, keep this vulnerable patient population's episodic vascular access care out of the hospital setting.

Clinical Background:

ESRD, commonly known as kidney failure, currently affects about 660,000 Americans and the number of ESRD prevalent cases is growing nationally at approximately 21,000 cases per year, according to the National Institute of Diabetes and Digestive and Kidney Diseases.[4]

Many ESRD patients suffer from underlying disease complications and multiple co-morbidities, resulting in poor health outcomes, high rates of hospital admission and readmission, and higher mortality rates. ESRD is predominantly caused by high blood pressure and/or diabetes and disproportionately affects minorities and lower socioeconomic classes. Compared to Caucasians, ESRD prevalence is significantly greater in African Americans, Native Americans, and Asian Americans.[5]

An ESRD patient has two options for survival: kidney transplantation or dialysis treatment. The predominant dialysis modality is hemodialysis, which patients typically receive in outpatient dialysis clinics three times a week for four hours at a time. At each hemodialysis treatment, a dialysis machine removes a large volume of blood from the patient's body, filters the blood through a dialyzer to mimic the function of the kidneys, and returns the filtered blood to the patient. A necessary component of hemodialysis treatment is the patient's vascular access, a shunt that accesses the patient's body blood.

Vascular accesses are surgically created vein and artery blood shunts that fall into three categories: central venous catheters ("CVCs"), arteriovenous grafts ("AVGs"), or arteriovenous fistulas ("AVFs"). See **Exhibit A**. CVCs and AVGs are synthetic shunts, whereas AVFs are constructed from the patient's own veins and arteries. CVCs are typically the first access a dialysis patient will receive because catheters allow immediate access, whereas AVGs and AVFs require anywhere from 3 to 6 months post-surgery to mature into functioning accesses. Despite the maturation period, AVGs and AVFs are preferable to CVCs because CVCs have the highest infection rates among available accesses. CVCs have approximately a 20% infection rate, AVGs a 10% infection rate, and AVFs less than a 0.5% infection rate.[6]

All vascular accesses, however, are susceptible to high dysfunction rates due to blockages, blood clots, and infection. The average dialysis patient experiences 1.6-2.7 access interventions per year in order to maintain a well-functioning access.[7] These figures are for average ESRD patients, including those who **do not** require interventions. Azura conservatively estimates an average ESRD patient will have 2.0 vascular access procedures per year, which include diagnostic procedures (e.g. fistulogram) that are not considered interventions. Petitioners' own experience is consistent. The Azura-affiliated centers in North Carolina performed 2.18 vascular access procedures per patient in 2017.[8] For ESRD patients on hemodialysis, vascular access is a

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[4] *See* https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

[5] *See* Footnote 4, above.

[6] Al-Jaishi A, Liu A, Complications of the Arteriovenous Fistula: A Systematic Review, *J Am Soc Nephrol,* 28: ____-____, 2016. doi: 10.1681/ASN.2016040412

[7] A 2004 study found averages of 2.77 intervention procedures per year for AVG patients and 1.6 procedures per year for AVF patients, with a RR of 3.13 for secondary interventions. *See* Perera GB, Mueller MP, Kubaska SM, Wilson SE, Lawrence PF, Fujitani RM. Superiority of Autogenous Arteriovenous Hemodialysis Access: Maintenance of Function with Fewer Secondary Interventions. *Ann Vasc Surg.* 2004;18(1):66-73. doi:10.1007/s10016-003-0094-y.

[8] See **Exhibit B** (data regarding vascular access procedures performed at Azura-affiliated centers in NC).

lifeline – but also an Achilles' heel. Without a functioning vascular access, patients cannot receive hemodialysis and are at risk of serious complications and death within 1-2 days.

Historically, dialysis access creation and maintenance required inpatient surgery, and the creation of vascular accesses is still performed primarily in a hospital setting. But since the early 2000s, dedicated, physician office-based vascular access centers have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within hours. Vascular access maintenance procedures are minimally invasive and use x-ray fluoroscopy to guide wires and catheters through blood vessels. Vascular access procedures for ESRD patients include angioplasty (to unblock clogged vessels at the access site), dialysis catheter management, thrombectomy, and stent placement. Azura-affiliated facilities' policy is to accommodate patients on a same-day basis, and in any event no later than the following day.

While vascular access centers are a demonstrated superior care model, new reimbursement rules have made the operation of vascular access centers in the physician office setting unsustainable, as detailed below. Therefore, licensed, vascular access ambulatory surgery centers ("vascular ASC") are necessary to preserve access to timely, cost effective care. Moreover, providing care in a licensed ASC would allow vascular ASCs to create vascular accesses, which are currently done in hospitals, in a less-expensive ambulatory setting and continue to keep overall health care spending on ESRD patients down by avoiding needless hospital admissions.

Dedicated Vascular Access ASCs Will Achieve Better Outcomes

Purpose-built vascular access centers like those operated by the Practices and Azura have a proven track record of improved clinical outcomes as a result of specialization and better coordination of care.

- A 2006 study examining the implementation of a vascular access center offering both vascular access creation and maintenance services in Phoenix, AZ, with a dialysis patient population of nearly 6,000, documented a demonstrated improvement in clinical outcomes, with approximately 0.6 fewer hospital days per patient year and decreased missed dialysis treatments of approximately 0.3 per patient year as compared to a national sample. *See* Mishler R, Sands JJ, Ofsthun NJ, Teng M, Schon D, Lazarus JM. Dedicated outpatient vascular access center decreases hospitalization and missed outpatient dialysis treatments. *Kidney Int.* 2006;69(2):393-398. http://www.ncbi.nlm.nih.gov/pubmed/16408132.

- A 2016 study comparing ESRD patients of Fresenius dialysis facilities who received vascular access care at a Fresenius Vascular Care affiliated access center to those who did not found that the hemodialysis patients who received care at an access center exhibited 33% lower 6-month mortality. *See* Han H, Chaudhuri S, Usvyat L, et al. Associations between coordinated vascular care visits and decreased rates of hospitalizations and mortality in hemodialysis patients. *J Vasc Access.* 2016;(17):e37-e64. Notably, these observations of improvements in outcomes are similar to previous findings reported by other institutions regarding the benefits of freestanding vascular access centers. *See, e.g.* Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing

dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial*. 2013;26(5):624-632. doi:10.1111/sdi.12120.

- A 2017 study examined 214,796 clinically and demographically similar Medicare patients for whom data was available through the United States Renal Data System (80,831 patients who received dialysis vascular access care primarily in freestanding office-based centers, and 133,965 patients who received dialysis vascular access care primarily in hospital outpatient departments). Across all outcome measures, patients treated in freestanding centers had better outcomes than those treated in Hospitals. The annual mortality rate for freestanding center patients was 15.1% lower than hospital patients, and the overall mortality across the entire study period was 10.9% lower in freestanding center patients. *See* El-Gamil AM, Dobson A, Manolov N, et al. What is the best setting for receiving dialysis vascular access repair and maintenance services? *J Vasc Access*. 2017;(18):e89-e118.

Azura-affiliated vascular access centers have offered this successful care model in North Carolina since approximately 2008, and the proposal here will further improve upon this model. Moving vascular access procedures to a licensed ASC will increase an already high standard of provider accountability. Conversion to an ASC will also enhance coordination of care. Currently, Petitioners' patients' vascular accesses are surgically created at hospitals – not because the services require a hospital setting or inpatient-level care, but because vascular access creation procedures are generally not reimbursed in the office setting. Petitioners are not aware of statewide or national data, but a Charlotte-based vascular surgeon affiliated with an existing vascular access center estimates 75% of new ESRD patients would be suitable to have initial access creation performed at an ASC.

A vascular access-focused ASC will allow providers to also perform access-creation procedures, resulting in integrated, coordinated care for dialysis patients. By permitting the same interventional care team to create, follow, repair and maintain the ESRD patient's vascular access in one specialized, regulated outpatient setting, the project will enhance the collaboration between dedicated ESRD providers, resulting in improved clinical outcomes and increased patient satisfaction. ESRD patients can have multiple co-morbidities that further complicate an already complex disease and require visits to multiple providers prescribing multiple care plans. As such, coordination of the ESRD patient's care plans is essential.

Because the proposed operating rooms would exclusively serve dialysis patients, the vascular ASC's providers will offer increased specialization and expertise in episodic vascular access procedures that hospitals cannot match. Forcing these patients into the hospital environment also exposes them to increased risk of infection and other complications and can have adverse implications for post-surgical recovery, potentially resulting in the need for extended and additional services.[9] Allowing for vascular ASCs to provide dialysis patients with the full-

[9] *See* Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial*. 2013;26(5):624-632. doi:10.1111/sdi.12120. *See also* El-Gamil A,

spectrum of vascular access care under the auspices of one integrated team of access specialists will optimize care and clinical outcomes for a fragile and complicated patient population.

Licensure of Vascular Access Centers as Ambulatory Surgical Facilities is Necessary to Preserve Access to Care

Azura-affiliated centers in North Carolina served 5,531 ESRD patients during 2017, including 13,377 patient visits and performed 12,054 vascular access procedures. Of the 5,531 total patients, 5,515 patients were North Carolina residents, which represents approximately 31% of North Carolina's total dialysis patient population of 17,789.[10] Patients of these centers received an average of 2.18 dialysis access procedures each during 2017.[11] 72.6% of the Azura patients were Medicare or Medicaid beneficiaries. Data regarding the composition of the procedures performed and the duration of these office-based surgical procedures is included as **Exhibit B**.

Considering only the volume of dialysis access procedures performed in the Azura-affilated centers in North Carolina in 2017, the resulting surgical hours would justify a need for nine ORs based on a threshold utilization of 1,312.5 hours per OR. *See* **Exhibit B**. If all North Carolina dialysis patients are considered, even conservatively assuming an average of 2.0 dialysis access procedures per patient and Azura's average case duration of .979 hours (59 minutes), the Statewide dialysis population of 17,789 suggests 35,578 procedures and 34,831 surgical hours, enough to demonstrate need for 26 ORs statewide based on the OR need methodology in the 2018 SMFP.

But despite the proven track record of purpose-built ESRD vascular access centers, this care model faces extinction as a result of severe cuts to CMS's physician fee schedule reimbursement for ESRD vascular access procedures. Reimbursement for these procedures was cut approximately 30% to 40% in the physician office setting effective January 2017.[12] While the 2018 Medicare reimbursement rates show a slight, single-digit increase to some of the vascular access CPT codes, overall the 2018 rates remain well below 2016 numbers.[13] While ASC rates for vascular procedures have also been cut, the differential between physician office rates and ASC rates remains significant.[14] Office-based vascular access centers are staffed and operate very much like a single-specialty ASC, including high levels of specialized staffing, and the drastic reimbursement cuts make it impossible for office-based vascular access centers to maintain sufficient staffing to provide the quality of care that ESRD patients need and to keep those patients out of the more costly hospital outpatient and emergency settings.

Dobson A, Manolov N, et al. What is the best setting for receiving dialysis vascular access repair and maintenance services? *J Vasc Access*. 2017;(18):e89-e118.

[10] See January 2018 N.C. Semiannual Dialysis Report, Table A.

[11] The procedure totals include only procedures performed at the Azura centers, and do not include dialysis access creation procedures, or other procedures performed in hospitals or at any other location.

[12] See **Exhibit C**, American Society of Diagnostic and Interventional Nephrology (ASDIN) Letter to Andrew Slavitt, August 22, 2016 (commenting on proposed CMS reimbursement cuts to dialysis circuit CPT codes 39601-39609); *see also* 81 Fed. Reg. 80170, 80290-96 (Finalizing 2017 Physician Fee Schedule reimbursement cuts to dialysis circuit CPT code RVUs as proposed).

[13] *See* 2018 Medicare Physician Fee Schedule Final Rule, 82 Fed. Reg. 52976 (November 15, 2017)

[14] *See* Note 14, above.

Consequently, it is no longer viable for physicians to develop or operate office-based vascular access centers, and existing office-based centers will ultimately cease providing these procedures or even close. In fact, numerous office-based vascular access centers nationwide have already shut down or are scheduled to close or be sold, approximately a year after the cuts took effect, including eleven vascular access centers across the Southern United States, nine in California and Nevada, and four in the Midwest (Kentucky, Ohio, Kansas and Minnesota), and two in Pennsylvania.

Additionally, numerous office-based vascular access centers that were previously profitable now operate at a loss as a result of the reimbursement cuts. In North Carolina alone, the Practices anticipate substantial capital calls at several centers operated by the Practices and Azura merely to be able to continue operations until the centers can become licensed as or develop ASCs.

If they cannot, the office-based centers cannot continue to operate at a loss indefinitely and will be forced to cease providing vascular access maintenance procedures, leaving dialysis patients no alternative but to receive surgical interventions in hospitals. This will lead to additional demand on valuable hospital resources, which will of course come with increased costs for patients and the health system overall.

In addition, the hospital is a less efficient, less effective environment for these services because hospitals are not designed to respond to the unplanned, though non-emergent nature of hemodialysis access procedures, given the broad scope of care they provide. In a hospital environment, ESRD patients in need of vascular access maintenance do not typically present as emergent cases, which can result in long delays in which they cannot dialyze and their condition deteriorates while waiting to receive necessary maintenance procedures. Specifically, in the experience of Azura-affilated physicians, ESRD patients in the hospital environment often are not seen "urgently" due to competing priorities of the hospital Interventional Radiology (IR) department – the service typically tasked with treating these issues. Urgent ESRD cases are typically scheduled at the end of the day in hospital IR departments as inpatients so that critically ill patients from the Emergency Department (ED) and Intensive Care Units (ICUs) can be accommodated first, along with previously scheduled IR outpatients. Further delaying care for this population is the fact that many hospital IR departments also require a potassium level be drawn. Furthermore, owing to their competing responsibilities, hospital IR departments often only temporize an urgent or emergent clotted fistula or graft merely by placing a catheter, until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization and the deleterious sequelae of using a catheter for dialysis. Not only can this put the patient's health at risk, it also compounds the already vast investment of time the ESRD patient must commit to life-sustaining dialysis.

Traditional, non-ESRD focused ASCs also suffer from many of the drawbacks of hospitals, and are therefore not a viable alternative for providing vascular access care. Non-vascular ASCs are less accessible to ESRD patients (which are approximately 80% Medicare and/or Medicaid) because ASCs typically rely on a high percentage of higher-reimbursing commercially insured patients and frequently have treatment criteria that rule out this patient population. For example, many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. ESRD patients typically suffer from 10-14 comorbidities and are classified as ASA

Physical Status III (indicating severe systemic disease).[15] Critically, traditional ASCs also schedule cases well in advance and cannot accommodate the urgent presentation of dialysis vascular access cases.

Integrating the full spectrum of vascular access services (from surgical access creation through full vascular maintenance) in a more regulated and convenient, Medicare-certified ESRD-focused ASC will preserve access to care in a more cost effective outpatient setting and improve coordination across the continuum of the ESRD patient's care while improving the hemodialysis patient's quality of life.

Vascular Ambulatory Surgery Centers Will Reduce the Cost of ESRD Care

According to the United States Renal Data System, ESRD beneficiaries comprised less than 1% of the Medicare population in 2014 but accounted for an estimated 7.2% of all Medicare fee for service spend, totaling over $32.8 billion.[16] Because most ESRD patients have complex health needs, multiple co-morbidities, and are heavy users of prescription drugs, they often must engage multiple providers, resulting in significantly higher per-patient costs of care across the health care system. Indeed, a typical ESRD patient costs the health care system nearly ten times more than the average Medicare patient.

In the past, providers were able to improve accessibility and quality while lowering overall costs by moving vascular access maintenance procedures from hospital settings to purpose-built physician office settings that functioned much like ASCs. For example, the 2013 Dobson study discussed above determined that the cost of care per patient per month for patients who received services at freestanding vascular access centers was, on average, $584 lower than for other patients; and the 2017 El-Gamil study likewise found (using a far larger sample size) that Medicare per member per month payments were $318 less for patients whose access care was primarily performed in freestanding centers, primarily because of fewer hospitalizations and dialysis treatments.[17]

Now these specialized unlicensed settings are no longer financially viable. Therefore efficient and proactive vascular access treatment– essential to reduce the expense to the health care system generally – requires ESRD-focused ASCs. Lacking an ASC environment, vascular access procedures will shift to hospitals, where cost of care and reimbursement far exceed that those in ASCs. See **Exhibit D** (comparison of 2018 OPPS and ASC reimbursement for dialysis access creation and maintenance procedures). Based on the volume and payor mix of procedures done in Azura-affiliated vascular access centers in North Carolina during 2017, doing those procedures in an ASC would save approximately $17,227,583 in Medicare and Medicaid reimbursement, compared with doing the same procedures in a hospital. See **Exhibit E** (impact analysis of 2017 procedures, if billed under CMS Hospital Outpatient Prospective Payment System or ASC Payment System). Based on North Carolina's historical ESRD population

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[15] See http://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system.

[16] United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016 (https://www.usrds.org/2016/view/v2_11.aspx).

[17] *See* Footnote 5, above.

growth, Azura expects the ESRD patient population to increase approximately 3.7% annually,[18] so these savings would show a corresponding increase over time.

By matching specialized resources to ESRD patients' medical needs and eliminating the unnecessary use of inpatient resources, ESRD-focused ASCs would generate additional cost savings – to the patient and the health care system. Studies confirm that access to appropriate outpatient and low-acuity resources can reduce hospital admissions and readmissions and improve patient outcomes, thereby reducing health care expenditures for the patients and the health care system overall.[19] On the other hand, unnecessary reliance on hospital care represents inefficient use of expensive resources and can unnecessarily fragment care and lead to increased potential for hospital readmissions, further driving up costs.

3.a. Adverse effects on population of the requested area likely to ensue if the adjustment is not made:

As noted above, without the requested adjustment to the methodology or, in the alternative, the need determination, ESRD patients' vascular access care will be forced into hospitals, at a greater cost to the healthcare system but without the specialization or coordination of care that a vascular ASC can provide. Moreover, it would unnecessarily consume limited hospital capacity and resources. Patients needing urgent dialysis procedures (e.g., declotting) who currently have access to office-based vascular access centers will lose access to timely care as those facilities close or cease offering those interventions, and will likely end up in hospital EDs and be admitted while waiting for care (at greater expense, yet increasing the chance of worse outcomes).

Moreover, vascular access creation procedures would remain in the hospital setting, foregoing the advantages in care coordination, improved outcomes and lower cost that a vascular ASC can provide.

3.b. Alternatives to the proposed adjustment that were considered and found not feasible:

1. Status Quo: The status quo is not feasible. As a result of CMS's reimbursement cuts under the 2017 Physician Fee Schedule, most office-based vascular access centers are no longer sustainable, and despite numerous closures of vascular access centers in 2017, CMS made no meaningful increases to the reimbursement provided under the 2018 Physician Fee Schedule. The existing vascular access centers in North Carolina are owned by physician practices with limited resources, which cannot continue offering these services at a loss indefinitely.

2. Apply to develop an ASC under existing OR need methodology. By statute, an ambulatory surgical facility in North Carolina must have at least one licensed OR.[20] The 2018 SMFP includes need determinations for additional ORs in only two of the counties in which

[18] Per the January 2018 Semiannual Dialysis Report, Table D, the statewide 5-year average annual change rate in the dialysis population is 3.7% (total dialysis patients statewide were 15,051, 15,574, 16,063, 16,851, and 17,387 in 2012-2016, respectively).

[19] See Footnote 4, above.

[20] *See* N.C. Gen. Stat. § 131E-176(1b).

Azura-affiliated vascular access centers are currently located (Mecklenburg and Wake). Four existing vascular access centers (in Caldwell, Cabarrus, Craven and Pitt Counties) cannot be approved for a vascular ASC CON in the foreseeable future under the current need methodology. Further, there are no OR need determinations in the 2018 SMFP in Health Service Area V or VI for which a vascular access ASC could be approved,[21] therefore ESRD patients in the Eastern part of the State would lack access to such a center. Moreover, there will likely be numerous competitive applications in 2018 for the ORs in Mecklenburg and Wake Counties, by hospitals and other surgical providers, and the number of approvable applications may well exceed the number of OR CONs that can be awarded, which could prevent the development of vascular ASCs despite the clear need.

3. Diversification of Unlicensed VACs. In response to a prior petition submitted by the Providers and Azura, the suggestion was made that the providers should diversify the services they offer in their unlicensed VACs. This suggestion is not reasonable or practical in most cases. The physicians in question are primarily interventional nephrologists; vascular access creation and maintenance is the core service they provide to patients.[22] To diversify, the physicians would have to develop new specialties, obtain new board certifications, and/or hire additional providers who practice in other fields.

Even if practical, such "diversification" would also undermine the proven benefit of dedicated facilities and specialized staff focused on ESRD patients and limit the facility time and staff available to serve this vulnerable population. The data regarding vascular access creation and maintenance demonstrates that patients who receive a majority of their dialysis vascular access care in an *ESRD-focused* facility have better outcomes, including fewer hospitalizations, fewer infections, lower mortality rates, and lower costs of care than patients who receive a majority of such care in a hospital outpatient department.[23]

4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.

The proposals in this petition would not result in unnecessary duplication because there are currently no ESRD-focused or vascular ASCs in North Carolina. Instead, VACs are existing, unlicensed physician office settings that are currently providing care to ESRD patients but whose ability to continue to do so is imperiled by Medicare reimbursement changes.

Moreover, the development of several vascular ASCs would not unnecessarily duplicate hospital surgical capacity because, as noted above in detail:

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[21] *See* 2018 SMFP, Chapter 6, Table 6C. The one-OR need determination in Cumberland County is the result of an adjusted need determination and is limited to hospital ORs used for training surgical residents.

[22] *See* G. Efstratiadis, et al. Interventional Nephrology: a new subspecialty of Nephrology. Hippokratia. 2007 Jan-Mar; 11(1): 22–24. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2464263 (noting concentration on vascular access and resulting improvement in timeliness and quality of vascular access services provided to ESRD patients as a result.)

[23] *See* Footnote 5, above.

1. Vascular access maintenance procedures do not require a hospital setting, and are mostly performed in physician offices now. Consequently, shifting maintenance procedures to licensed ASCs will not adversely affect hospital surgical utilization.

2. Dialysis access creation procedures are currently performed as an incidental part of hospitals' broader surgical services, and are often secondary to more emergent and clinically intensive surgeries.[24] Therefore, shifting some dialysis access creation procedures to licensed vascular ASCs would improve patient care and outcomes, and reduce the cost to the healthcare system by providing care in a less expensive outpatient setting, but would not have any significant impact on hospital surgical utilization.

Further, these proposals would not unnecessarily duplicate existing ambulatory surgical facilities because:

1. Existing ASCs generally cannot accommodate ESRD patients, who are chronically ill, generally with multiple co-morbidities, and who have frequently missed scheduled dialysis treatments;

2. Existing ASCs' scheduling processes generally cannot accommodate vascular access procedures as they usually present urgently;

3. Non-ESRD focused ASCs lack the specialized clinical staff to provide care with the efficiency and expertise that can be achieved in a vascular ASC.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value.

Safety and Quality: The conversion of unlicensed VACs to single-specialty vascular access ASCs through either a change in the need methodology or the implementation of a demonstration project would improve provider accountability by moving vascular access procedures from the office environment to the more highly-regulated ASC environment. Moreover, a lack of licensed vascular ASCs as office-based vascular access centers close will drive ESRD patients to hospitals, which often cannot provide timely care and where the risk of complications and infections is much higher. As noted above, there is extensive evidence that specialized vascular access centers result in better clinical outcomes than other settings.

Access: As noted above, if vascular ASCs cannot be developed, office-based vascular access centers will either cease offering vascular access maintenance procedures or close, and ESRD patients will lose access to the fast, effective, and high-quality care those facilities currently provide. Instead, care will be driven to the hospital setting, where patients usually cannot be seen on an urgent basis. These lifesaving services are of particular importance to medically

[24] E.g., dialysis creation procedures are not among the most common surgical procedures performed in North Carolina hospitals as reflected on the Department's hospital licensure renewal application form.

underserved groups, including ethnic and racial minorities, who disproportionately suffer from ESRD.[25]

The creation of licensed vascular ASCs would also improve access to high-quality vascular access creation procedures with better care coordination, better clinical outcomes and lower cost than the hospital setting in which they are currently provided.

The proposed demonstration project would also promote geographic access by including a need determination for vascular ASCs in all six Health Service Areas statewide, while a change in the need methodology to exclude Dedicated Vascular Access Operating Rooms from the operating room inventory and need methodology would likewise permit providers across the state to serve dialysis patients in all areas.

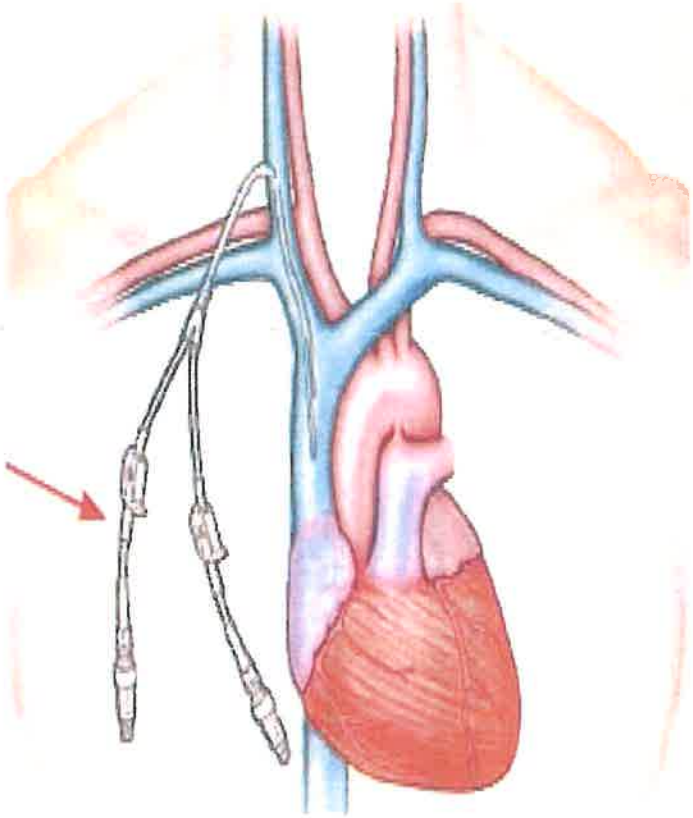
Value: If the status quo persists, existing vascular access centers will be forced to stop offering access maintenance procedures, and care will be driven to the more expensive hospital setting, including numerous procedures for indigent patients that are currently provided by vascular access centers free of charge. Also, the inability of hospitals to see patients as quickly as vascular access centers for urgent vascular access maintenance issues will result in patient complications, hospital admissions and expensive care that would be unnecessary if ESRD patients had urgent access to licensed vascular ASCs.

As noted above, CMS reimburses ASCs hundreds or thousands of dollars per procedure less than in the hospital setting, which would save Medicare and Medicaid over $17M in reimbursement in North Carolina alone based on 2017 procedures. Accordingly, licensed vascular access ASCs would save North Carolina's healthcare system tens of millions per year.

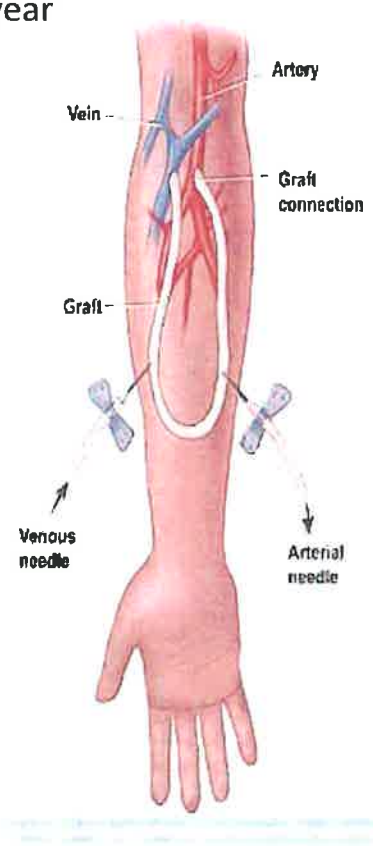
[25] See Footnote 4, above.

3 types of Vascular Access

Catheter: Most problematic
High frequency of bloodstream infections



Graft: Moderately problematic.
Synthetic material gets infected at 10% per year



Fistula: Least problematic. Natural vein gets infected at 0.5% per year

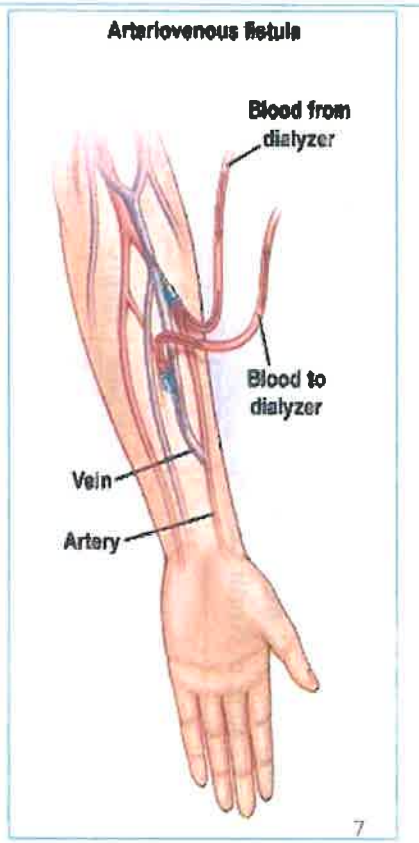


EXHIBIT A

Exhibit B – Supporting Data for Petition

A. Case volumes and duration for common vascular access procedures – Azura-affiliated vascular access centers in North Carolina.

	2016		2017	
Procedure Type	**Total Cases**	**Total Case Hours**	**Total Cases**	**Total Case Hours**
PTA - ESRD	5,277	5,277	6,568	6,568
Catheter Change - ESRD	428	428	424	424
Catheter Removal - ESRD	736	736	827	827
Catheter Insertion - ESRD	407	407	497	497
Catheter Other - ESRD	77	77	82	82
Fistulogram - ESRD	1,170	975	1,433	1,194
ESRD Other	104	104	85	85
ESRD Coil Embolization	55	69	102	128
Stents - ESRD	785	589	1,091	818
Thrombectomy - ESRD	827	1,034	945	1,181
Total	9,866	9,695	12,054	11,804
Average Hours per Case		0.983		0.979
Avg. Case Time in Minutes		59		59
Surgical Hrs (Cases x Avg. Time/60)		9,695		11,804
Surgical Hours Per Year Per OR		1,312.50		1,312.50
OR Need		7.4		9.0

Source: Azura data for 2016 and 2017 for existing facilities in Cary, Raleigh (HSA IV), Greenville, New Bern (HSA VI), Charlotte and Concord (HSA II).

B. Breakdown of vascular access type among NC ESRD patients:

% of pts with central venous catheter (CVC)	18.77
% of pts with arteriovenous fistula (AVF)	60.84
% of patients with arteriovenous graft (AVG)	20.39

Source: Current Fresenius Kidney Care data for all ESRD patients receiving treatment at FKC dialysis centers in North Carolina.

C. Proportion of NC ESRD patients likely to require vascular access intervention yearly: Azura's experience nationally is that approximately 70% of ESRD patients require ESRD interventional procedures in a given year. However, this figure does not include dialysis access creation or diagnostic procedures (e.g., fistulogram), which could be performed in an ASC.

D. Most common interventions and relative proportions:

	2016	2017
Procedure Type	**Total Cases**	**Total Cases**
PTA - ESRD	5,277	6,568
Catheter Change - ESRD	428	424
Catheter Removal - ESRD	736	827
Catheter Insertion - ESRD	407	497
Catheter Other - ESRD	77	82
Fistulogram - ESRD	1,170	1,433
ESRD Other	104	85
ESRD Coil Embolization	55	102
Stents - ESRD	785	1,091
Thrombectomy - ESRD	827	945
Total:	9,866	12,054

	2016	2017
Procedure Type	**% of Total**	**% of Total**
PTA - ESRD	53.5%	54.5%
Catheter Change - ESRD	4.3%	3.5%
Catheter Removal - ESRD	7.5%	6.9%
Catheter Insertion - ESRD	4.1%	4.1%
Catheter Other - ESRD	0.8%	0.7%
Fistulogram - ESRD	11.9%	11.9%
ESRD Other	1.1%	0.7%
ESRD Coil Embolization	0.6%	0.8%
Stents - ESRD	8.0%	9.1%
Thrombectomy - ESRD	8.4%	7.8%
Total:	100.0%	100.0%

Source: Azura data for 2016 and 2017 for existing facilities in Cary, Raleigh (HSA IV), Greenville, New Bern (HSA VI), Charlotte and Concord (HSA II).

ASDIN
AMERICAN SOCIETY OF DIAGNOSTIC AND INTERVENTIONAL NEPHROLOGY

August 22, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1654-P
P O Box 8013
Baltimore, Maryland 21244-8013

RE: File Code-CMS-1654-P; Payment Policies under the Physician Fee Schedule & Other Revisions to Part B For CY 2017; Proposed Rule; (July 15, 2016)

Dear Acting Administrator Slavitt:

The American Society of Diagnostic and Interventional Nephrology (ASDIN) appreciates the opportunity to comment on the 2017 Proposed Physician Fee Schedule. **We specifically wish to address the CMS proposals related to the Dialysis circuit family of CPT codes 369x1, 369x2, 369x3, 369x4, 369x5, 369x6 and 369x7.** CMS did not accept the RUC recommendation regarding the valuation of both physician work and practice expense portions of the codes. We believe that the proposed RVUs are incorrect, and if not adjusted will have severe ramifications for the care of ESRD patients moving forward.

Background

ASDIN is a national medical society with approximately six hundred physician members and one hundred and twenty-five associate members whose focus is the provision of dialysis access care for patients with end-stage renal disease. Our members practice in both hospital and non-hospital settings, performing dialysis access procedures such as angiography, angioplasty, and thrombectomy which assist in the creation, maintenance, and repair of dialysis access. Because of service, quality, and cost considerations, these procedures are often done by our members in specialized vascular centers which are part of the physician office (site of service 11). These highly

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Journal of Vascular Access is the official journal of the
American Society of Diagnostic and Interventional Nephrology

EXHIBIT C

focused office-based centers have been demonstrated to provide tremendous value by increasing access to timely procedures, performing continual patient education, coordinating with patients' nephrologist and dialysis facility, and ensuring excellent outcomes. This allows patients to remain on dialysis without disruption due to vascular access complications. Studies have shown that the care patients receive in these centers is of high quality, and has reduced both overall hospitalization and costs to Medicare.

- *Dobson, A. et al Clinical and Economic value of Performing Dialysis Access Procedures in a Freestanding Office-based center as compared with the Hospital Outpatient Department among ESRD beneficiaries. Seminars in Dialysis. 2013.*

We are concerned that the dramatic reductions (see appendix A) in valuation for CPT codes 369x1 through 369x7 in the Physician Fee Schedule (PFS) proposed rule for 2017 would, if finalized, severely threaten the viability of these vascular access centers and lead to both increased costs and disruption of a system of care that has been very positive for patients with kidney disease. Ultimately, this disruption will lead to reduced patient access to timely care and overall reduction in the quality of care received.

Physician Work RVUs

A number of our members participated in the RUC survey of the Dialysis circuit family of codes through their membership in the Renal Physicians Association (RPA). We agree with the RPA comments to the 2017 proposed rule related to the Dialysis Circuit family of codes (369x1 – 369x9). During the survey process, our members recognized a significant problem with the survey that we believe is unique to the Dialysis circuit codes. This survey issue is particularly important because CMS has based its rejection of the RUC recommended physician work RVUs particularly for code 369x1 (the base code in this family) on concern about maintaining appropriate relativity with the Open and Percutaneous Transluminal angioplasty family of codes 372x1 – 372x4. We wish to point out a significant difference between these code families that we believe impacts the work intensity of the Dialysis circuit codes – and makes it appropriate for the dialysis circuit codes to have higher IWPUT as was in the RUC recommended RVUs.

According to CPT, the Dialysis access circuit is defined as originating in the artery adjacent to the arterial anastomosis and including all venous outflow (whether single or multiple veins) to the axillary-subclavian vein junction. We agree with this definition of the dialysis access because each component is integral to having a functional fistula or graft. While several different arteries and veins may be included in this definition, from a functional perspective it is a single "vessel." Hence, it is appropriate to treat the dialysis access as a single vessel for coding purposes and that is how the bundled Dialysis circuit codes (369x1 – 369x6) are built – they include all imaging and intervention within the dialysis access. The dialysis access as defined has a greater propensity for multiple lesions than native vessels in part because of the arteriovenous physiology and in part because it is cannulated with needles on a regular basis. Because of this greater propensity for multiple lesions, it is appropriate to define the access vessel as CPT has done and allow reporting of only a single angioplasty or stent in that entire conduit. This means that there is no code to recognize the work of "additional vessel" angioplasty or stent placement. There is also no code to recognize the additional work of arterial versus venous angioplasty. This is very different than the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). Add-on codes 372x2 and 372x4 describe arterial or venous

angioplasty (respectively) in each additional named vessel. This allows the building of a survey tool with a "typical" vignette with one angioplasty procedure, but appropriately allow reporting the additional work of intervention in a second or third lesion in separate vessels.

However, the survey built on the "typical patient" (51% of the cases) in the Dialysis circuit code family 369x1 – 369x6 is unable to recognize the additional work of additional angioplasty or stent – even though multiple or arterial lesions occur with significant frequency. The higher intensity (IWPUT) of these codes compared to the Open and Percutaneous Angioplasty codes 372x1 and 372x3 reflects the work of treating these additional lesions within the dialysis circuit.

We believe that taking these differences into consideration, the RUC recommended work RVUs for codes 369x1 – 369x6 maintain appropriate relativity between the Dialysis circuit code family (369x1 – 369x6) and the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). We ask that CMS accept the RUC recommended RVUs for codes 369x1, 369x2, 369x3, 369x4, 369x5, and 369x6.

Additionally, since the CMS proposed lower work RVU for 369x7 is based upon comparison to these codes, **we ask that CMS accept the RUC recommended RVUs for 369x7.**

Practice Expense

We believe that the RUC recommended PE inputs for the nine CPT codes in the Dialysis circuit family (369x1 – 369x9) should be accepted and disagree with the refinements proposed by CMS. These are discussed individually in the following paragraphs.

Additional preservice clinical labor time for CPT codes 369x4 – 369x6 (Thrombectomy codes)
These codes describe procedures performed on an urgent basis in a patient with a thrombosed dialysis access. This is different than codes 369x1 – 369x3 which describe procedures performed electively on patients with a dysfunctional dialysis access. The elective procedures are scheduled and planned well in advance of the procedure and performed on days that do not conflict with the patient's dialysis schedule. However, the urgent procedures (369x4 – 369x6) are typically done when a patient presents to their dialysis treatment with a thrombosed access. They are unable to receive dialysis and an urgent call is placed by the dialysis facility to request thrombectomy. These procedures are typically done the same day so that the patient can receive dialysis within 12-24 hours and avoid hospitalization. The urgent nature of the procedure, need for additional preoperative testing because of missed dialysis, and need for arranging unscheduled dialysis treatment requires additional preservice time of the procedural staff. Arranging for an off schedule dialysis treatment is typically the responsibility of the procedural staff after the patient has been assessed in the preoperative area and the plan to restore or obtain dialysis access has been determined.

L037D Clinical labor to prepare and position patient
The RUC proposed additional 3 minutes are reasonable because these cases are done on the upper extremity using portable c-arm fluoroscopy. The additional time includes prepping and positioning the arm, applying appropriate shielding to the patient's torso, positioning the c-arm unit, and then positioning other radiation shielding devices. Prepping the arm can be done in a number of fashions but

typically requires 2 staff members. One staff member dons sterile gloves and holds the patient's arm extended to the side and up off the arm board (many ESRD patients cannot hold their arm in this position for the time required to fully prep). Another staff member then preps the arm and hand including fingers with Chloraprep applicators, applies a sterile glove or towel to cover the hand, and then the patient's arm is lowered into position on the arm board where it can be further draped for the procedure. Each of these activities require more time in the arm case than procedures done in the long plane of the body including the torso and legs. Three minutes is a more accurate reflection of the additional time than CMS's proposed one minute.

Thrombectomy device (Treretola)

A mechanical thrombectomy device (Arrow Trerotola device is most typical, SA015) and a Fogarty thrombectomy balloon (SD032) are both used in a dialysis access thrombectomy because they serve different purposes. The typical thrombosed fistula has an irregular vessel diameter that is filled with thrombus. A thrombectomy device is used to macerate this thrombus so that it can be aspirated or lysed. A pharmacologic agent may also be given to aid in thrombus lysis. This must be done prior to establishing inflow by removing the fibrin plug that forms at the arterial anastomosis. Once thrombus lysis through the body of the access is completed, it is safe to re-establish inflow by passing a Fogarty balloon catheter across the arterial anastomosis, inflating the balloon, and dragging it back into the access through the anastomosis. This maneuver dislodges the fibrin plug, allowing flow into the access. The Fogarty balloon is small and highly compliant allowing it to be pulled through the artery and into the access without damaging the vessels. The thrombectomy device cannot be used safely for this function. This device is larger so risks pushing the fibrin plug into the artery if passed across the arterial anastomosis from the access – risking distal arterial embolization. The device is also much more rigid being made from metal and with irregular shape that risks damaging the endothelium of the artery causing arterial injury. The Arrow Trerotola device packaging specifically warns against using it within the native artery. The Fogarty balloon also is not effective as a thrombus maceration device because of its small size. Both a thrombectomy device and Fogarty balloon are required in the typical fistula thrombectomy case.

Covered stent (Gore Viabahn SD254)

Covered stents are the only stent devices that are FDA approved and supported by evidence from randomized controlled trials for use in dialysis access procedures. They are typically used in recurrent or elastic stenoses in dialysis access – and have become the standard of care for these interventions. They are also used to repair venous rupture caused by balloon angioplasty. This is the reason that a covered stent is included in 369x3 and 369x6. Bare metal stents are still used in central venous angioplasty because of concern that covered stents will occlude the internal jugular vein. That is the reason that the Cordis bare metal stent is included in 369x8.

- *Haskal ZJ, Trerotola S, Dolmatch B, Schuman E, Altman S, Mietling S, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. N Engl J Med. 2010;362(6):494-503.*
- *Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. J Vasc Surg. 2016.*

Hemostatic patch

Two hemostatic patches are required in thrombectomy procedures (369x4 – 369x6) because these procedures require two separate cannulations and sheaths. Opposing sheaths are placed in the access to allow clearing of thrombus in both the arterial and venous portions of the access. The two sheaths also allow imaging and interventions on the entire access. At the end of the case, both sheath sites are removed and covered with a hemostatic patch which aids in preventing bleeding and maintaining sterility.

Chloraprep applicator 26ml

Skin antisepsis prior to percutaneous and open interventions is critical to infection prophylaxis. This is especially important for ESRD patients who have a higher risk of Staphylococcal infections. In the past, povidone iodine has been the most widely used antiseptic for skin cleansing prior to catheter insertion (1). However, studies have shown that preparation of central venous sites with a 2% aqueous chlorhexidine gluconate (in 70% alcohol) is superior for skin site preparation to either 10% povidone-iodine or 70% alcohol alone (2-6). In 2002, the CDC recommended that 2% chlorhexidine be used for skin antisepsis prior to catheter insertion (7). Although not specifically recommended for other interventional procedures, Chloraprep (2% Chlorhexidine gluconate in isopropyl alcohol) has become the typical solution used to prepare the arm and access site for these procedures (369x1 – 369x9). It has demonstrated superiority in preventing procedure related infections due to better antimicrobial properties and more prolonged effect on the skin. Chloraprep is different than Hibiclense solution which is 4% Chlorhexidine (no alcohol). The combination of Chlorhexidine and isopropyl alcohol has greatest efficacy as preoperative skin prep in dialysis catheter and endovascular procedures. Because of this greatest efficacy and CDC recommendations (for catheters), Chloraprep has become standard of care for the Dialysis circuit family of procedures.

1. *Clemence MA, et al. Central venous catheter practices: results of a survey. Am J Infect Control 1995;23:5.*
2. *National Kidney Foundation. Clinical Practice Guidelines for vascular access. Am J Kidney Dis 2006;48(Suppl 1):S176-273.*
3. *O'Grady NP, et al. Guidelines for the prevention of intravascular catheter-related infections. Am J Infec Control. 2011;39(4 Supple 1):S1-34.*
4. *Maki DG, et al. Prospective randomized trial of povodine-iodine, alcohol, and chlorhexidine for prevention of infection associated with central venous and arterial catheters. Lancet. 1991;338(8763):339-43.*
5. *Chaiyakunapruk N, et al. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site are: a meta-analysis. Ann Intern Med. 2002;136(11):792-801.*
6. *Mimoz O, et al. Prospective randomized trial of two antiseptic solutions for prevention of central venous or arterial catheter colonization and infection in intensive care unit patients. Crit Care Med. 1996;24(11):1818-23.*
7. *O'Grady NP, et al. Guidelines for prevention of intravascular catheter related infections. Atlanta, GA, Centers for Disease Control and Prevention. 2002:1.*

Wires

369x1 – 369x3 would typically utilize a micropuncture introducer kit that includes a 0.018" wire, a starter Bentson type 0.035" wire, and a hydrophilic 0.035" wire. Thrombectomy cases (369x4 – 369x6) require an additional 0.035" wire to cross the arterial anastomosis for imaging of the arterial inflow and interventions (commonly occurring) on the arterial side of the access. Once flow is established in the access by means of thrombectomy, a wire and catheter are passed through the access and across the arterial anastomosis so that contrast can be injected directly into the feeding artery. This allows one to

image the peri-arterial dialysis access safely without risking embolization of retained thrombus if an occlusive retrograde contrast injection technique were to be used. Central venous angioplasty cases (369x7 – 369x8) require an additional 260cm wire in order to have adequate length to park the tip in the inferior vena cava. Placing the wire tip in this location is an important safety maneuver to ensure that the wire remains fully across the angioplasty site (in case of rupture) and does not extend into or through the right ventricle causing arrhythmia or bleeding into the pericardium.

Conclusion

Finally, we wish to point out that the cumulative impact of reimbursement reductions for the Dialysis circuit family of codes 369x1 – 369x9, both in terms of physician work and practice expense RVUs, is quite dramatic (see appendix A). If the 2017 proposed work and PE RVUs are implemented many outpatient access centers that focus on providing care for ESRD patients may no longer be able to operate. Having dedicated centers with ability to respond rapidly to immature, dysfunctional, and thrombosed accesses has been critical in improved outcomes seen in the past few years including increased prevalent native arteriovenous fistulas, decreased catheter use, and lower inpatient hospitalization for vascular access complications (USRDS data). Migration of the Dialysis circuit family of codes 369x1 – 369x7 back to the hospital setting will greatly increase cost to the Medicare Program. **We strongly urge CMS to avoid the drastic reimbursement changes that would interrupt the progress made to date and create such challenges for our patients.**

We want to thank CMS for the opportunity to comment on the 2017 Physician Fee Schedule Proposed Rule. We look forward to working with you to ensure the best outcomes for Medicare beneficiaries with ESRD.

Sincerely,

Kenneth Abreo, MD
President
ASDIN

EXHIBIT E

CONE HEALTH
The Network for Exceptional Care

Strategic Development
1200 North Elm Street
Greensboro, NC 27401-1020
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March 22, 2017

Christopher G. Ullrich, M.D., Chair
NC State Health Coordinating Council
c/o Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Comments Regarding a Petition for Vascular Access Ambulatory Surgical Centers for ESRD Patients

Dear Dr. Ullrich:

Cone Health appreciates the opportunity to comment on the petition filed by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology, PA (the practices) and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (Azura) (collectively the Petitioners) to change the need methodology for the 2019 State Medical Facilities Plan or add an Adjusted Need Determination for a Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients. Cone Health supports the standard OR need methodology as presented in the 2018 State Medical Facilities Plan (SMFP), and urges the SHCC to deny the petition.

Sincerely,

James Roskelly

James Roskelly
Executive Vice President, Strategic Development
Cone Health

Attachment

Comments on the Petition for a Change in the Need Methodology for the 2019 State Medical Facilities Plan or, in the Alternative, an Adjusted Need Determination for a Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients

Cone Health urges the NC State Health Coordinating Council (SHCC) to deny the referenced petition. The Petition provides no evidence to support the need to change the operating room need methodology in the 2019 State Medical Facilities Plan (SMFP). The petition also provides no evidence to support the need for single specialty ambulatory surgery centers (ASC) dedicated to vascular access in North Carolina.

SMFP Operating Room Need Methodology

Cone Health supports the standard operating room need methodology that was updated in 2017 and is found in Chapter 6 of the 2018 State Medical Facilities Plan (SMFP). Furthermore, since the 2018 SMFP is the first edition to utilize this updated need methodology, Cone Health does not believe any changes should be made until data are available to quantify the impact of this revised methodology. Specific to the Petition, Cone Health does not believe that the Petitioners have demonstrated the need for changes to the approved need methodology or an adjusted need determination and have based the petition on unsubstantiated claims throughout.

No Evidence to Support Need

The Petition fails to provide any clinical evidence to support the claim that vascular access procedures currently performed in office-based vascular access centers (VAC) now require a licensed operating room (OR). In fact, the Petitioners state on p. 1 that "As discussed in detail herein, physicians have long operated unlicensed vascular access centers in the physician office setting…Due to recent Medicare reimbursement changes, however, it is no longer financially feasible for many VACs to continue operation." It has not historically been the practice of the SHCC to change planning assumptions and methodologies simply to respond solely to Medicare reimbursement changes.

The Petitioners make misleading claims about delays in care in the hospital setting. On page 11, the Petition states, "[u]rgent ESRD cases are typically scheduled at the end of the day in hospital IR departments as inpatients." This statement contains false analogies and statements. First, the Petitioners indicate their policy is to see patients needing vascular access procedures on the same day or the next day. There cannot be a delay attributed to the hospital for waiting until the end of the day compared to Petitioner's ability to see the patient the following day. In some cases, the hospital could perform the procedure before the Petitioner based on their policy and based on the 24/7 nature of an acute care facility. Second, the Petitioners

indicate that the procedures are performed as inpatient procedures with no facts supporting this claim.

The Petition Does Not Support the Basic Principles of the SMFP

The SMFP contains three (3) basic principles governing the plan: safety/quality, access, and value. While the Petitioners analyze the petition from the lens of ESRD patients only, the SMFP and the SHCC are responsible for all North Carolinians.

Safety/Quality

The Petitioners fail to address concerns about patient safety. The petition contains multiple references to the complex health status of ESRD patients on pages 11-12, including the high number of co-morbidities these patients have. The Petitioners state that many existing non-ESRD focused ASCs will not accommodate patents with an ASA III score, but they do not offer any evidence as to how vascular access ASCs would overcome the anesthesia challenges that existing multi-specialty ASCs currently face with chronic co-morbid patients.

Access

The North Carolina Office of State Budget and Management estimates the current population of North Carolina is 10,155,942 as of July 2016, the most recent certified estimates available. The January 2017 North Carolina Semiannual Dialysis Report contains the number of ESRD patients receiving in-center treatment as of June 30, 2016 as 15,184. The overall percentage of North Carolinians on dialysis treatment is 0.15%. Therefore, less than two-tenths of one percent of North Carolinians might benefit from increased access to operative services proposed in this petition. If these patients were currently unable to access these services, they could benefit from increased access. However, the petitioner does not provide compelling evidence that patients cannot access these services now.

Value

The Petitioner states multiple times throughout the petition that the impetus behind the request is a reimbursement change from CMS that reduced the reimbursement under the physician fee schedule for these procedures. By the very nature of the proposal, the Petitioners are asking to move these procedures to a higher cost setting. The Petitioners acknowledge this on page 10 of the petition by stating, "the differential between physician office rates and ASC rates remains significant." One of the key considerations for designating higher ASC and HOPD rates compared to physician offices is due to the amount of overhead necessary to operate a higher acuity facility. As stated previously in this section, only 0.15% of North Carolinians would be eligible for treatment at these new ASCs. As such, they would be most impacted by the increased costs and overhead associated with these ASCs.

In summary, the Petition fails to make a persuasive argument to justify either an operating room methodology change or an adjusted need determination for a demonstration project for vascular access ASCs for ESRD patients. Thus, Cone Health respectfully requests that the Petition be denied.

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March 19, 2018

Mark Payne, Director
NC DHHS – Division of Health Service Regulations
2001 Mail Service Center
Raleigh, NC 27699-2001

Dear Mark:

I am working on behalf of Wake Forest Baptist Hospital in opposition to the attached Petition of Fresenius Dialysis which seeks to create single specialty ambulatory surgery facilities from existing physician office-based unlicensed Vascular Access Centers. The Petition claims the recent rate reductions by CMS in Dialysis Vascular reimbursements make it likely that many office-based Vascular Outpatient Centers may no longer be able to operate.

The Petition seeks to either grant these Vascular Access Centers an exclusion from the Certificate of Need methodology for Ambulatory Surgery Centers or an adjusted need determination for a demonstration project for two operating rooms in each of the six Health Service Areas statewide which will be authorized to provide an expanded range of vascular services including those currently being provided only in hospital settings.

One of my major concerns with the Fresenius proposal is that it is designed to fully control the health care setting of the approximately 18,000 North Carolina residents undergoing dialysis by putting a very substantial number of such patients into six proposed vascular access operating rooms to be built across the State. This proposal will absolutely remove critical patients from their local hospitals in the rural areas of our State from receiving procedures currently required to be provided to them in the hospital setting.

I think it is critical for the SHCC to investigate the financial impact on our rural hospitals of the proposed changes in procedures being taken from our rural hospitals. I am very aware that our rural hospitals particularly in the Northeastern part of our State provide many services to the dialysis population. That part of their patient population may be critical to the continued existence of those rural hospitals.

Please let me know if I can provide you any additional information with respect to this matter. I strongly believe that we need to support all of our rural hospitals and to keep them as a central part of their local communities.

Best wishes.

Sincerely,

John T. Bode

EXHIBIT F

Acute Care Services Committee
Agency Report
Exemption to Methodology for Vascular Access Operating Rooms
Proposed 2019 State Medical Facilities Plan

Petitioners:
The Practices and Azura:

American Access Care of NC, PLLC
Eastern Nephrology Associated, PLLC
Metrolina Nephrology Associates, PA
North Carolina Nephrology, PA
Fresenius Vascular Care, Inc., d/b/a Azura Vascular Care

Contact:
Murat Sor, MD
Chief Medical Officer
Azura Vascular Care
52 East Swedesford Road, Suite 110
Malvern, PA 19355
610-644-8900
murat.sor@azuracare.com

Request:
The Practices and Azura (Petitioners) propose a change in the operating room (OR) need methodology such that "dedicated vascular access operating rooms located in single-specialty ambulatory surgical facilities be excluded from the [State Medical Facilities Plan] SMFP's annual operating room inventory" (page 1). The Petitioners note that applicants would still be required to "demonstrate need and comply with the [certificate of need] CON standards applicable to operating rooms" (page 1).

The Petitioners alternatively propose an adjusted need determination for a demonstration project to develop a total of 12 ORs, two in each of the six Health Service Areas (HSA). The ORs would be located "in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for [end-stage renal disease] ESRD patients…" (page 1). The criteria in the discussion of the demonstration project indicate the proposal to serve patients with chronic kidney disease (CKD) as well.

Background Information:
Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Healthcare Planning receives petitions twice during the course of plan development. Early in the planning year, petitioners may request changes that have the potential for statewide impact, defined as "the addition, deletion, and revision of policies or projection methodologies" (p.7, 2018 SMFP).

A functioning vascular access (VA) is essential for patients who receive dialysis. The three types of VA for ESRD patients are central venous catheter, arteriovenous (AV) graft, and AV fistula. The Petitioners report that 61% of their patients in North Carolina have an AV fistula, 19% have a central venous catheter, and 20% have an AV graft. The National Kidney Foundation recommends the use of AV fistulas whenever feasible because they are associated with the lowest rate of complications.[1] Vascular access centers (VAC) provide the surgical creation, management, and maintenance of VAs for ESRD patients. Some centers may also provide other vascular procedures for other types of conditions (e.g., peripheral arterial disease).

Fresenius owns and/or operates approximately 52% of the dialysis facilities in the state. Other major providers are DaVita with 36% of facilities and Health Systems Management with 8%. Various providers account for the remaining 4% of facilities. Fresenius also operates VACs, but DaVita and Health Systems Management do not.[2] Although no official information is available on the number of VACs in the state, one comment received by the Agency reported that there are approximately 12.

Persons with ESRD are eligible for Medicare regardless of age. The impetus for the petition is that the Centers for Medicare and Medicaid Services (CMS) instituted bundled payments for VA procedures on January 1, 2017. Specifically, procedures performed together more than 75% of the time must be bundled for payment. The Society for Vascular Surgery claims that a fee-for-service system produces an inherent incentive for physicians to treat immediate problems only. Rather, the purpose of bundling is to "target the highest quality vascular access method for a given patient" and then to "set up a bundled/global payment that incorporates placement of the vascular access as well a maintenance of this access over some defined period of time."[3] Note that the payment system applies to all types of VA reimbursement, not only those for ESRD patients. The Petitioners contend that many VACs will close because of the financial burdens of this change. They further state that closures would force ESRD patients into hospitals, thus incurring higher costs and poorer patient outcomes.

The Agency does not have systematic data on where VA procedures currently take place in North Carolina. VACs are not licensed, and the Agency collects no data on their procedures. The Agency's annual License Renewal Applications (LRA) do not identify vascular surgical procedures in sufficient detail to ascertain the type of procedure or patient. However, LRAs from ASCs indicate that only about 0.2% of the total surgical procedures performed were vascular. Hospital outpatient departments (HOPD) also report that about 0.2% of the total procedures were vascular. Note that the HOPD figures do not include ambulatory procedures performed in shared

[1] http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm
[2] DaVita owns Lifeline VACs in other states; the closest center to NC is in Norfolk, Virginia.
[3] https://vascular.org/news-advocacy/svs-medicare-physician-payment-plan-2013

ORs in a hospital. Based on these statistics, it appears that most VA procedures are probably performed in VACs.

The Practices and Azura submitted a petition in the summer of 2017 requesting a demonstration project, almost identical to the one requested in the current petition. The Agency recommended denial, and the Acute Care Committee and SHCC concurred. The rationale for the denial was twofold. First, a number of questions remained that were not addressed in the petition. Second, sufficient time did not exist for proper consideration of the proposed demonstration project. The SHCC normally takes one full cycle to consider a demonstration project. For example, before approving the Single Specialty Ambulatory Surgical Facility Demonstration Project, the SHCC established a workgroup that began consideration of the demonstration in November of 2008. The project was approved for implementation in the 2010 SMFP. More recently, consideration of the Dental Ambulatory Surgical Facility Demonstration Project began in March 2016, with implementation in the 2017 SMFP.

Analysis/Implications:

Estimated Need for ORs for Vascular Access Procedures

NC had 17,789 dialysis patients as of 6/30/2017.[4] This population grows by approximately 3.5% annually. Based on Azura's national experience, about 70% of ESRD patients need VA interventions. Patients in this 70% need about 2 interventions per year, with an estimated 60 minutes per procedure. It is unknown whether Azura's estimates include turnaround time.[5]

The following calculations use the Petitioners' figures presented in Exhibit B and the current OR methodology:

- 17,789 x 70% = 12,453 patients
- 2 procedures per patient = 24,906 procedures
- 60 minutes per procedure = 24,906 surgical hours
- 1312.5 surgical hours = full utilization of an OR in an ASC
- 24,906 ÷ 1312.5 =18.98→19 ORs

Based on these calculations, VA procedures for ESRD patients may currently require 19 ORs. This estimate uses the full utilization assumption for ASCs. The full utilization assumptions for hospitals are higher, and are based on the total number of surgical hours for the facility. Therefore, using the ASC full utilization percentage provides an estimate of the minimum number of ORs. Although the above estimates indicate that approximately 19 ORs may be required to serve the VA needs of ESRD patients, this estimate does not imply the need for 19 additional ORs. The estimate also does not imply that all ORs should be in ASCs, even though this illustration uses the ASC utilization threshold.

[4] North Carolina Semi-Annual Dialysis Report, January 2018.

[5] Other internet-based sources report 30-45 minute case times, but it is unclear exactly which procedures were included in the estimates.

Two potential groups of patients mentioned in the Petition were not included in the above calculations. First, the Petitioners propose to serve patients with CKD, but provide no estimate of the potential number and type of procedures expected. Second, the Petition also points out that initial VA placement in ASCs would be suitable for approximately 75% of new ESRD patients. Based on the estimated 3.5% annual growth in the ESRD population, the state would see approximately 623 new cases in 2018. If 75% can have initial VA placement in an ASC, this would increase the estimated number of patients by 467. Since no information on the length of these procedures was available, they were not included in the above estimates of the number of patients who may need interventions after initial access placement.

Impact of Recent CMS Regulations on Vascular Access Centers

The stated goal of the bundled payment structure for VA procedures is to have a zero percent impact on nephrology reimbursement overall.[6] Several sources have estimated that the new regulations will decrease revenue by an average of 30-40% for VA procedures for ESRD patients, when performed in a physician's office.[7] Moving VA procedures from a procedure room in a medical practice to a hospital outpatient setting will incur significant additional costs to Medicare. To the extent that patients shift to inpatient settings, they may also be at greater risk of health care-associated infection. Therefore, developing freestanding ASCs is one solution being sought across the nation.[8] See Attachment A for a more detailed discussion of the issues.

After the 2017 rates went into effect, industry groups and professional associations engaged with CMS to address the consequences of the new payment structure and to seek changes. New CMS payment rates went into effect January 1, 2018. According to one group of attorneys who represent physicians and VACs, "[t]he 2018 reimbursement rates continue to place significant financial pressure on physicians who provide dialysis vascular access services in a Place of Service-11 (POS-11), vascular access center (VAC) or office-based laboratory (OBL) setting, while at the same time significantly decreasing any site-specific financial benefit of providing such services in a Medicare-certified ambulatory surgery center (ASC)."[9] Some individuals in the industry have reported that CMS plans further changes to the rate structure in 2019, but this information cannot be verified.[10]

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[6] Riley, James B. & Greis, Jason S. (2016). Practical Considerations for Medical Practices Considering Converting their Vascular Access Centers into Medicare-Certified Ambulatory Surgery Centers. Chicago: McGuireWoods LLP.

[7] Neumann, Mark E. (2016, September 29). *Nephrology: News & Issues.* Proposed bundling in Medicare Fee Schedule could cut interventional access revenue up to 40%.

[8] Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

[9] Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

[10] Litchfield, Terry & McKitrick, Jason. (2017, November 7). Webinar: Analysis of 2018 Medicare Reimbursement Rates for Vascular Procedures. Retrieved from: https://www.mcguirewoods.com/Events/Firm-Events/2017/12/Analysis-2018-Medicare-Reimbursement-Rates-Vascular-Procedures.aspx

National data on the effects of the new CMS regulations is not yet available. Anecdotally, in 2017, the American Society of Diagnostic and Interventional Nephrology (ASDIN) reported that 20% of 71 VACs surveyed by the organization have closed as a result of the new regulations, and another 20% are likely to close.[11] It is unknown where patients of these closed VACs continue to receive services.

Issues Concerning Development of Dedicated Vascular Access ASCs

The Petitioners present a case for the development of new ambulatory ORs that specialize in serving the VA needs of patients with CKD and ESRD. If greater OR capacity is needed to serve these patients, three methods exist:

1. Convert unlicensed procedure rooms in VACs to licensed ORs.
2. Develop (build) new ORs in ASCs or hospitals.
3. Prioritize ESRD patients in ORs in existing ASCs or hospitals.

The first two options require a CON and a need determination in the SFMP, while the third does not. Moreover, the lead time for the first two options could easily be two years to completion. The third option is likely to require less time.

In general, the first option may best fit the business model of VACs, especially those with procedure rooms built to OR standards. However, having a licensed OR transforms the VAC from a physician's office into an ASC, which has different accreditation and regulatory requirements. This model would not be preferred in areas of the state that lack VACs with procedure rooms. Reportedly, dialysis patients in the western part of the state typically receive VA services in hospitals, rather than VACs.

In terms of the second option, the 2018 SMFP includes need determinations for 29 new ORs.[12] Past experience shows that new ASCs with fewer than two ORs tend not to be financially viable. However, CON applications have been approved for a single OR in an existing facility; in some cases, applicants have proposed to convert a procedure room into an OR. This option is open to VACs, as it is to all other CON applicants. While the CON review process may appear to give preference to multispecialty ASCs, it is possible for applicants to make a compelling case for single specialty facilities. Also, the summer petition process allows anyone to apply for an adjusted need determination if they believe that the methodology does not meet the needs of patients in a particular service area or region.

The third option would likely require a formal partnership with an existing ASC or hospital. The Petitioners point out that ASC scheduling does not allow for the often emergent need for VA procedures. They also note that not all ASCs accept ESRD patients, especially those who have

[11] Litchfield, Terry & McKitrick, Jason. (2017, November 7). Webinar: Analysis of 2018 Medicare Reimbursement Rates for Vascular Procedures. Retrieved from: https://www.mcguirewoods.com/Events/Firm-Events/2017/12/Analysis-2018-Medicare-Reimbursement-Rates-Vascular-Procedures.aspx (The original source for the survey is not available, thus it is not possible to know when it was conducted. It is only known that the survey does not cover the full 2017 calendar year. In addition, this survey probably does not have comprehensive coverage, because it is likely that ASDIN's national membership includes physicians from far more than 71 VACs.)

[12] One additional need determination exists for training of surgical residents in inpatient and outpatient procedures, and thus is not available to all types of applicants.

missed a dialysis treatment. In addition, ASCs may not have all of the equipment required for VA procedures (e.g., C-arm). The Petition does not discuss formal partnerships, but it is a reasonable option that may be advantageous to both the VA providers and the existing facility.

The Petition expresses a clear preference for the development of dedicated VA ORs in free-standing ASCs versus ambulatory ORs in a hospital. Given that one goal of the planning process is to avoid unnecessary duplication of services, the Agency undertook an examination of potential surplus capacity in ASCs and the distribution of 2018 SMFP OR needs. Figure 1 shows the number and location of surplus ORs in ASCs in North Carolina, as reported in the 2018 SMFP. This figure includes only multispecialty licensed ASCs with at least 1.5 surplus ORs; by definition, it excludes GI endoscopy facilities, demonstration sites, single specialty ASCs, and HOPDs. The calculated number of surplus ORs is 32.45. With the understanding that not all surplus ORs sit idle, the Agency conservatively estimates that the state has about 20 surplus ORs. The western part of the state is not well represented in Figure 1, but most other areas are. Figure 1 also shows the service areas that have OR needs in the 2018 SMFP. Here, the western part of the state is better represented.

Demonstration Project Alternative

The Petitioners also proposed a demonstration project as an alternative to the methodology change. The purpose of this type of demonstration appears to be to show that a certain model of service provision is successful, but the Petition offers no discussion what would constitute "success." In this case, it does not seem necessary to demonstrate that an ASC can operate under the criteria proposed in the Petition.

Agency Recommendation:

Analysis of the available data led to two conclusions: (1) the CMS payment system is in a period of uncertainty such that no single solution is optimal; and (2) several viable alternatives to the Petitioners' request exist in the current SMFP methodology.

Persons knowledgeable of the payment system and CMS have noted that the changes from 2017 to 2018 complicated the issues surrounding converting VACs into ASCs. In 2017, conversion to ASCs may have been a more clear option for VACs, all other things being equal. However, the 2018 changes may have made that preference somewhat less clear.[13]

Even if VACs have procedure rooms built to OR standards, conversion does not occur immediately. It is likely take at least a year from now to accomplish, depending on the CON review cycle. Further, development of new ORs pursuant to a permanent change to the methodology would take approximately two years to implement fully. The existing inventory of ORs in ASCs indicates that the state likely has sufficient capacity to accommodate most of the need. While operators of VACs may not prefer the third option discussed above, it is nevertheless an option that the SHCC has proposed to petitioners in the past. Moreover, it normally can be completed more quickly than conversion of procedure rooms or development of new ORs.

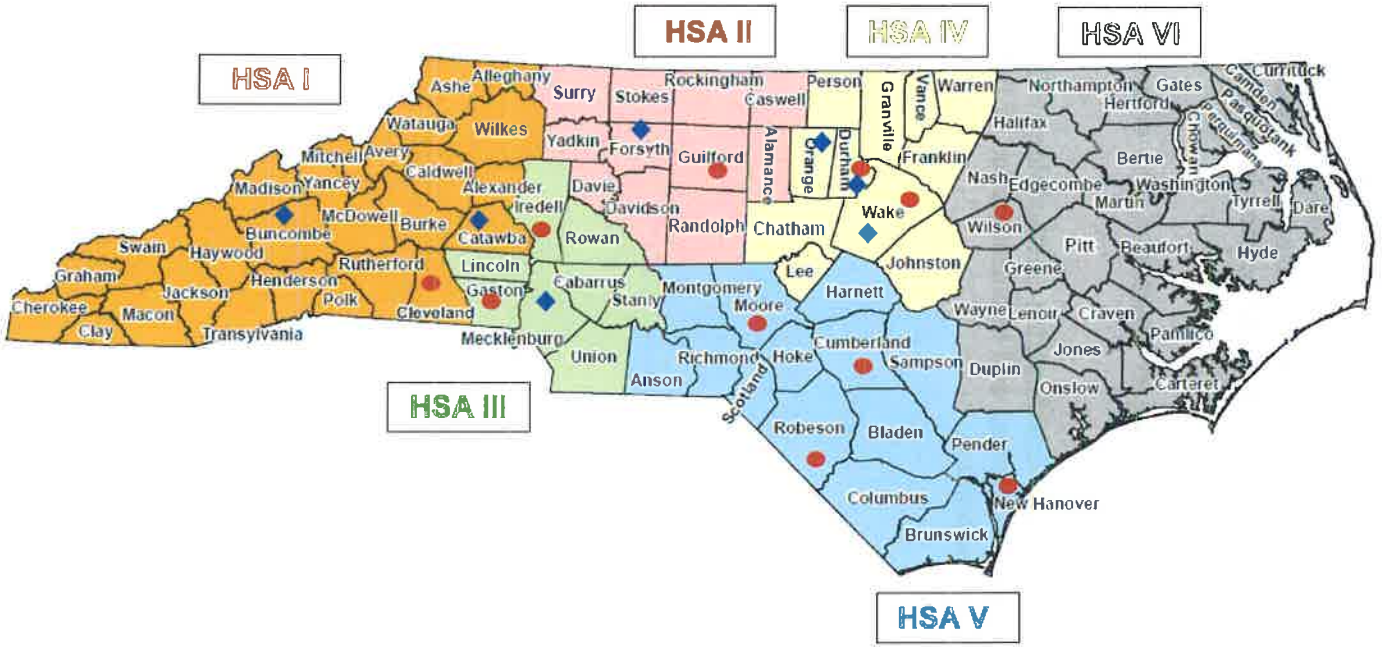
[13] Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

The OR methodology underwent substantial revision in 2017. The SHCC has typically been reluctant to make changes in a methodology so soon after its implementation. Altering the new methodology before it is has an opportunity to function seems short-sighted. In lieu of partnering with existing ASCs that have surplus ORs, providers of VA services to ESRD patients can partner with an applicant for one of the ORs in the 2018 SMFP. As noted above, surpluses do not exist in all areas of the state. If a practice believes that patients are not being served well in a particular area of the state, submission of an adjusted need determination petition in the summer is always an option.

The Agency also considered the demonstration project alternative, but determined that the proposed demonstration would not be informative.

The Agency supports the current OR need determination methodology. Given available information and comments submitted by the deadline, and in consideration of factors discussed above, the agency recommends denial of the petition.

Figure 1. Multispecialty Ambulatory Surgical Centers with Surplus Operating Rooms, 2018 SMFP



● County with Surplus OR(s) ◆ County with OR Need Determination in 2018 SMFP

HSA I	HSA II	HSA III
Cleveland: Cleveland Ambulatory Surgery Center - 4*	Guilford: High Point Surgery Center – 2.70 Guilford: Surgical Center of Greensboro – 1.58	Gaston: CaroMont Specialty Surgery – 4.12 Iredell: Iredell Surgical Center – 3**
HSA IV	**HSA V**	**HSA VI**
Durham: James A. Davis Amb. Surgical Center – 3.63 Wake: Blue Ridge Surgery Center- 2.76 Wake: Capital City Surgery Center – 2.26	Cumberland: Fayetteville Amb. Surgical Center – 2.46 Moore: Surgery Center of Pinehurst – 1.55 Robeson: Surg. Ctr. at SE Health Park – 2.36	New Hanover: Wilmington SurgCare – 1.66 Wilson: Eastern Regional Surgical Center – 3.37

* Chronically underutilized facility with 6 ORs. Current utilization is slightly over 1 OR (based on 1,312.5 hours).

** Chronically underutilized facility with 4 ORs. Current utilization is less than 1 OR (based on 1,312.5 hours).

Note: The need determination shown in Buncombe County covers the Buncombe/Madison/Yancey multicounty service area. The map does not include the need determination in Cumberland County because the ORs are restricted to the training of surgical residents.

Attachment A

McGUIREWOODS

2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL Into an ASC Even More Challenging

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November 10, 2017
(Updated November 13, 2017)
www.mcguirewoods.com

Earlier this month the Centers for Medicare and Medicaid Services (CMS) issued the 2018 Medicare Physician Fee Schedule (MPFS) and Ambulatory Surgical Center Fee Schedule (ASCS), which included updates to payment policies, payment rates and quality provisions for services furnished during the 2018 calendar year. The 2018 reimbursement rates continue to place significant financial pressure on physicians who provide dialysis vascular access services in a Place of Service-11 (POS-11) vascular access center (VAC) or office-based laboratory (OBL) setting, while at the same time significantly decreasing any site-specific financial benefit of providing such services in a Medicare-certified ambulatory surgery center (ASC).

Significant changes in reimbursement for dialysis vascular access care were first implemented in 2017 by CMS as a result of a new payment policy requiring services billed together more than 75 percent of the time to be bundled. The following interventional CPT code bundles were developed, which resulted in significant Medicare reimbursement reductions for a variety of commonly performed interventional services:

Procedure	2016 CPT Codes	2016 FFS Reimbursement	2017 Bundled CPT Code	2017 MPFS (POS-11) Reimbursement	% Change (2016-2017)
Angiogram of access	36147	$855	36901	$581	-32%
Angiogram with angioplasty	36147 35476 75978	$2,052	36902	$1,235	-40%
Angiogram with stent	36147 37238	$4,712	36903	$5,663	17%
Thrombectomy	36147 36148 36870	$2,567	36904	$1,801	-30%
Thrombectomy with angioplasty	36147 36148 36870 35476 75978	$3,222	36905	$2,304	-20%
Thrombectomy with stent	36147 36148 36870 37238	$5,701	36906	$6,868	17%

These dramatic reimbursement cuts made it financially difficult for many physicians to continue providing dialysis vascular access care in a POS-11 setting and, as a result, a significant number of VACs and OBLs closed in 2017 and additional centers are slated to close in 2018. It is

widely believed that a significant number of VACs and OBLs that exclusively provided dialysis vascular access care (and which do not perform peripheral arterial disease (PAD) services) experienced a net financial loss of between — 10 percent and 0 percent in 2017 in providing these services, depending upon a center's patient volume, case mix and payor mix.

A number of trade groups and organizations, including the Renal Physicians Association (RPA), the Dialysis Vascular Access Coalition (DVAC) and the American Society of Diagnostic and Interventional Nephrology (ASDIN), actively engaged with CMS to advise the agency of the consequences of its reimbursement changes, including decreased availability of quality office-based care for this at-risk patient population, and increased cost to the Medicare program resulting from patients receiving dialysis access-related services in more expensive hospital outpatient departments. In an attempt to address the medical needs of this critically vulnerable patient population, some providers have considered the financial, operational and legal viability of converting their VAC or OBL into a Medicare-certified ASC and/or expanding their service offering to include PAD and other interventional procedures consistent with a physician's relevant training and experience. The table below highlights the difference in 2017 Medicare reimbursement for certain dialysis vascular access services performed in an office-based VAC or OBL, as compared to the same services performed in an ASC setting:

Procedure	Bundled CPT Code	2017 MPFS Final Rate	2017 ASC Final Rate	$ Differential
Angiogram of access	36901	$581	$520	$61
Angiogram with angioplasty	36902	$1,235	$3344	$2109
Angiogram with stent	36903	$5,663	$6,334	$671
Thrombectomy	36904	$1,801	$3,474	$1673
Thrombectomy with angioplasty	36905	$2,304	$6471	$4167
Thrombectomy with stent	36906	$6,868	$9,861	$2993

Based upon the 2018 MPFS rates it appears that these organizations' concerns have been addressed in a limited manner. CMS has made modest increases in Medicare reimbursement for services performed in an ASC or OBL in 2018 as demonstrated in the following table:

Procedure	Bundled CPT Code	2018 MPFS Final Rate	2016 MPFS Final Rate	2017 MPFS Final Rate	$ Change (2016-2018)	$ Change (2017-2018)
Angiogram of access	36901	$611	$855	$581	-$244	$30
Angiogram with angioplasty	36902	$1,272	$2,052	$1,235	-$780	$37

Angiogram with stent	36903	$5,725	$4,712	$5,663	$1,013	$62
Thrombectomy	36904	$1,849	$2,567	$1,801	-$718	$48
Thrombectomy with angioplasty	36905	$2,344	$3,222	$2,304	-$878	$40
Thrombectomy with stent	36906	$6,949	$5,701	$6,868	$1,248	$81

The financial impact of the 2018 MPFS rates presents a "mixed bag" of news. When compared against the 2017 MPFS reimbursement rates, CMS made minor positive reimbursement changes to the entire crosswalk of dialysis vascular access codes, including to the industry's most commonly billed CPT code (36902), which will experience a 3 percent reimbursement increase versus the 0.8 percent decrease that was originally proposed in the 2018 Proposed Rule. However, when the 2018 MPFS reimbursement rates are compared against the 2016 MPFS reimbursement rates one can see that 2018 Medicare reimbursement for a significant number of the most commonly used dialysis vascular access codes still falls far below 2016 reimbursement rates.

CMS also unexpectedly made significant reimbursement cuts to codes for dialysis vascular access services performed in an ASC setting in 2018 when it released the 2018 Final ASCS, which changes had not been previously discussed in the 2018 Proposed ASCS earlier this year. Industry groups continue reaching out to CMS to voice their concern about these reimbursement cuts, which may continue to enhance the problem of patients seeking out dialysis vascular access care in a more expensive hospital outpatient department setting. According to Jan Dees, President of American Vascular Access, a national provider of VAC and OBL services, "it is estimated there are 30 million patients in the United States in need of procedures impacted by these and other similar CPT codes. It is therefore critically important for patients to have easy access to VAC and OBL sites of service that can continue to provide conveniently located, high quality, timely and lower cost services."

Yet, despite this decrease in Medicare reimbursement for dialysis vascular access care provided in an ASC setting, there continues to be a significant reimbursement differential between dialysis vascular access care provided in an OBL or VAC as compared against care provided in an ASC:

Procedure	Bundled CPT Code	2018 MPFS Final Rate	2018 ASC Final Rate	$ Differential
Angiogram of access	36901	$611	$495	$116
Angiogram with angioplasty	36902	$1,272	$2,776	$1504
Angiogram with stent	36903	$5,725	$4,414	$861
Thrombectomy	36904	$1,849	$2,913	$1064
Thrombectomy with angioplasty	36905	$2,344	$4,947	$2603

Thrombectomy with stent	36906	$6,949	$7464	$515

These Medicare reimbursement changes come at a time when many providers are considering converting their VACs and OBLs into Medicare-certified ambulatory centers as we discussed in a recent Whitepaper entitled Practical Considerations for Medical Practices Considering Converting Their Vascular Access Centers Into Medicare-Certified Ambulatory Surgery Centers. These reimbursement changes and the possible eventual elimination of site-of-service payment reimbursement differentials by CMS across outpatient care settings as CMS moves to site-neutral payments, will only make conversion decisions more challenging.

Jason Greis is a partner in the McGuireWoods Healthcare Department.

Jake Cilek is an attorney in the McGuireWoods Healthcare Department.

EXHIBIT G

Exhibit 4

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
http://www.ncdhhs.gov/dhsr/

Beverly Eaves Perdue, Governor
Wilma A. Dehn, Acting Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

November 27, 2012

Mr. Frank Kirschbaum
Nexsen Pruet, LLC
4141 Parklake Avenue, Suite 200
Raleigh, NC 27612

RE: Surgical Care Affiliates v. DHHS, 12 CVS 09409 and 12 CVS 010478

Dear Mr. Kirschbaum,

Subject to any applicable statutory dollar thresholds, The North Carolina Department of Health And Human Services, Division of Health Service Regulation, has determined that procedure rooms will solely be regulated in licensed ambulatory surgical facilities and hospitals, and only to the extent required to ensure that such procedure rooms meet the requirements of the Federal Life Safety Code as referenced in the North Carolina Administrative Code. Neither the Acute and Home Care Licensure and Certification Section, nor the Construction Section will require any determination from the Certificate of Need Section prior to authorizing the use or establishment of a procedure room.

Sincerely,

Drexdal Pratt, Director
Division of Health Service Regulation

EXHIBIT H

North Carolina Department of Health and Human Services
Division of Health Service Regulation

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

July 31, 2017

Randi L. Shults
3916 Ben Franklin Boulevard
Durham, NC 27704

Exempt from Review

Record #:	**2345**
Facility Name:	North Carolina Specialty Hospital
FID #:	943374
Business Name:	North Carolina Specialty Hospital
Business #:	1328
Project Description:	Renovation and expansion to include decontamination, clean work and sterile supply areas, expansion of procedure room and development of an additional procedure room, repositioning of support spaces, reconfiguration of equipment storage area in the operating room suite, relocation of two licensed acute care beds and add necessary support space, conversion of the space occupied by the relocated acute beds to unlicensed observation beds, and expansion of the 2nd floor to accommodate five unlicensed observation beds
County:	Durham

Dear Ms. Shults:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 10, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

Effective January 01, 2017, this license is issued to

North Carolina Specialty Hospital, LLC

to operate a hospital known as

North Carolina Specialty Hospital

located in Durham, North Carolina, Durham County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 943374

License Number: H0075

Bed Capacity: *18*

General Acute 18

Dedicated Inpatient Surgical Operating Rooms: 0
Dedicated Ambulatory Surgical Operating Rooms: 0
Shared Surgical Operating Rooms: 4
Dedicated Endoscopy Rooms: 0

NORTH CAROLINA since 1926
SPECIALTY HOSPITAL
Proudly Physician Owned
3916 Ben Franklin Boulevard • Durham, NC 27704
P.O. Box 15819 • Durham, NC 27704

Bernetta Thorne-Williams, Project Analyst
Health Planning and Certificate of Need Section
Division of Health Service Regulations, DHHS
Mail Service Center 2704
Raleigh, NC 27699-2704

RE: Updated Exemption Notice / Renovations and expansion of health service facility pursuant to NCGS § 131E -184(g) / North Carolina Specialty Hospital / Durham County

Dear Ms. Thorne-Williams:

Thank you for sending the attached letter "Exempt from Review, Record # 2291" dated June 9, 2017. (Please see Exhibit 1.) North Carolina Specialty Hospital (NCSH) is submitting a new exemption notice because the hospital intends to change the scope of the project that includes increases in capital cost, modification of the design of the project and increases in the number of square feet to be constructed. The updated plans are included and document the intent of NCSH to renovate and expand specific portions of the main hospital to improve workflow and enhance patient care. NCSH is requesting confirmation that this renovation is exempt from Certificate of Need review pursuant to NCGS § 131E -184(g).

NCGS § 131E -184(g) states that *The Department shall exempt from certificate of need review any capital expenditure that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E -176(16)b. if all of the following conditions are met:*
(1)The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.
(2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.
(3)The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

The sole purpose of the capital expenditure is to renovate and expand portions of the existing health service facility of North Carolina Specialty Hospital that are located on the main campus. The scope of the project involves renovation and new construction to accomplish the following changes to the existing hospital facility:

- Expand the decontamination, clean work, and sterile supply spaces
- Increase the size of an existing procedure room within the operating room suite
- Develop an additional procedure room within the operating room suite
- Reposition support spaces such as a clean linen, soiled hold, and bio-hazard rooms, as well as a reconfiguration of an equipment storage area in the OR suite
- Relocate two licensed acute care beds within the hospital and add necessary support space
- Convert two existing acute care beds to become unlicensed observation beds
- Enlarge the second floor to accommodate five unlicensed observation beds

Increasing the size of the sterile supply spaces is necessary to accommodate the workload due to the high utilization of the four existing shared operating rooms. The procedure room expansion and addition are also needed to respond to increases in procedure room utilization for pain management and other minimally invasive procedures. The reconfiguration of the clean linen, soiled hold, bio-hazard rooms and equipment storage allows for the procedure room changes as well as improved workflow and efficiency.

The relocation of two licensed acute care beds into a new suite will provide the appropriate space to serve high acuity medical and surgical inpatients on an as-needed basis. With the relocation, two existing licensed patient rooms will be delicensed and become observation beds. Five additional unlicensed observation beds are incorporated into the expansion plan on the second floor of the hospital. Having a total of seven additional unlicensed observation beds will be helpful to respond to periods of high census that occur often. When an observation patient occupies a licensed acute care bed the hospital is unable to admit an inpatient into that licensed bed.

The cost of the renovation and expansion project, including the equipment, is expected to be $8,240.109. A certified cost estimate is provided in Exhibit 2. Floor plans of the existing facility and the proposed project at completion are included in Exhibit 3. The following table summarizes the renovations and new construction:

NCSH Main Campus Hospital	Existing S.F.	Addition - New Construction S.F.	Renovation S.F.	Total S.F. at Completion
1st Floor	39,544	2,154	3,139	42,683
2nd Floor	16,667	3,640	1,931	20,307

The renovation and expansion project will not result in a change of bed capacity or the addition of a health service facility or new institutional health service other than that allowed in NCGS § 131E - 176(16)b. North Carolina Specialty Hospital will continue to be licensed for eighteen medical surgical acute care beds, and four operating rooms. As seen in Exhibit 4 the development of a procedure room is not subject to Certificate of Need. The project will not result in the acquisition of major medical equipment or the offering of health services not currently provided. The only items projected to cost more than $10,000 each include sterile supply equipment, procedure room lights and patient monitoring equipment.

NCGS § 131E -176(14n) *provides "main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:*
a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The proposed project involves changes to the first floor and second floor renovations at the main campus of North Carolina Specialty Hospital that is located at 3916 Ben Franklin Blvd, Durham, NC 27704. Financial and administrative control is provided in the offices physically located in the first floor of this same main campus. The locations of the financial officer and administrative officer at the main campus are highlighted in the facility plans. North Carolina Specialty Hospital is a licensed health services facility (DHSR Acute Care Licensed No. H0075).

This request shall serve as prior written notice of the proposed capital expenditure and includes documentation to support that this request meets the exemption criteria. Please do not hesitate to contact me at (919) 956-9301 if you need additional information. Thank you for your consideration of this information.

Sincerely,

Randi Shults
Chief Executive Officer

Exhibits for NCSH Exemption Notice

Exhibit 1 - Exempt from Review Record, # 2291

Exhibit 2 - Certified Cost Estimate Form

Exhibit 3 - Floor plans for the proposed project at completion.

Exhibit 4 - Copy of letter from Drexdal Pratt, DHHS to SCA regarding procedure rooms

Exhibit 1

North Carolina Department of Health and Human Services
Division of Health Service Regulation

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

June 9, 2017

Randi L. Shults
3916 Ben Franklin Boulevard
Durham, NC 27704

Exempt from Review

Record #:	**2291**
Facility Name:	North Carolina Specialty Hospital
FID #:	943374
Business Name:	North Carolina Specialty Hospital
Business #:	1328
Project Description:	Renovation and expansion to include decontamination, clean work and sterile supply areas, expansion of procedure room and development of an additional procedure room, repositioning of support spaces, reconfiguration of equipment storage area in the operating room suite, relocation of two licensed acute care beds and conversion of two licensed acute beds to unlicensed observation beds
County:	Durham

Dear Ms. Shults:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 2, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Bernetta Thorne-Williams

Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

EXHIBIT Z - PROJECTED CAPITAL COST

Project Name: North Carolina Specialty Hospital Renovations and Expansion

Proponent: North Carolina Specialty Hospital, LLC

A.		**Site Costs**				
	(1)	Full purchase price of land		N/A		renovation
		Acres _____ Price per Acre		N/A		renovation
	(2)	Closing costs		N/A		renovation
	(3)	Site Inspection and Survey		$8,000		
	(4)	Legal fees and subsoil investigation.		$2,000		
	(5)	Site Preparation Costs				
		Soil Borings	$2,500			
		Clearing-Earthwork	$28,000			
		Fine Grade For Slab	$700			
		Roads-Paving	$10,000			
		Concrete Sidewalks	$5,000			
		Water and Sewer	$5,000			
		Footing Excavation	$3,200			
		Footing Backfill	$3,200			
		Termite Treatment	$700			
		Selective Demolition	$12,500			
		Sub-Total Site Preparation Costs		$70,800		
	(6)	Other (Specify)		N/A		
	(7)	**Sub-Total Site Costs**			**$80,800**	
B.		Construction Contract				
	(8)	Cost of Materials				
		General Requirements	$31,500			
		Concrete/Masonry	$142,500			
		Doors & Windows/Finishes	$1,094,000			
		Thermal & Moisture Protection	$51,000			
		Equipment/Specialty Items	$65,000			
		Mechanical/Electrical	$1,578,000			
		Structural Steel	$330,000			
		Sub-Total Cost of Materials		$3,292,000		
	(9)	Cost of Labor		$3,082,132		
	(10)	Permit		$10,500		
	(11)	**Sub-Total Construction Contract**			**$6,384,632**	
C		Miscellaneous Project Costs				
	(12)	Building Purchase		N/A		renovation
	(13)	Fixed Equipment Purchase/Lease		$577,683		
	(14)	Movable Equipment Purchase/Lease		$681,095		
	(15)	Furniture		$10,000		
	(16)	Landscaping		$12,000		
	(17)	Consultant Fees				
		Architect and Engineering Fees	$400,000			
		Commissioning	$18,900			
		Equipment Planning	$36,000			
		Reimbursible Expenses	$30,000			
		Legal Fees	N/A			in-house
		Market Analysis	N/A			in-house
		Material Testing	$5,000			
		Sub-Total Consultant Fees		$489,900		
	(18)	Financing Costs (e.g. Bond, Loan, etc.)		N/A		
	(19)	Interest During Construction		N/A		
	(20)	Impact Fees		$4,000		
	(21)	**Sub-Total Miscellaneous**			**$1,774,677**	
D.		**Total Capital Cost of Project**				**$8,240,109**

I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.

_____ Date Certified: 29. Jun. 2017

(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

_____ Date Signed June 29, 2017

(Proponent - Signature of Officer) (Title of Officer)

Exhibit 4

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center ▪ Raleigh, North Carolina 27699-2701
http://www.ncdhhs.gov/dhsr/

Beverly Eaves Perdue, Governor
Aldona Z. Dela, Acting Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

November 27, 2012

Mr. Frank Kirschbaum
Nexsen Pruet, LLC
4141 Parklake Avenue, Suite 200
Raleigh, NC 27612

RE: Surgical Care Affiliates v. DHHS, 12 CVS 09409 and 12 CVS 010478

Dear Mr. Kirschbaum,

Subject to any applicable statutory dollar thresholds, The North Carolina Department of Health And Human Services, Division of Health Service Regulation, has determined that procedure rooms will solely be regulated in licensed ambulatory surgical facilities and hospitals, and only to the extent required to ensure that such procedure rooms meet the requirements of the Federal Life Safety Code as referenced in the North Carolina Administrative Code. Neither the Acute and Home Care Licensure and Certification Section, nor the Construction Section will require any determination from the Certificate of Need Section prior to authorizing the use or establishment of a procedure room.

Sincerely,

Drexdal Pratt, Director
Division of Health Service Regulation

EXHIBIT I

NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

May 1, 2019

Christine Washick, Administrator
Triangle Orthopaedics Surgery Center
7921 ACC Boulevard
Raleigh NC 27617

Exempt from Review

Record #:	**2923**
Facility Name:	Triangle Orthopaedics Surgery Center
FID #:	101146
Business Name:	Triangle Orthopaedics Surgery Center, LLC
Business #:	1892
Project Description:	Renovate and expand the surgery center to add two unlicensed procedure rooms
County:	Wake

Dear Ms. Washick:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 23, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Triangle Orthopaedics Surgery Center

EmergeOrtho, P.A. affiliate organization: Triangle Division

April 23, 2019

Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Notice of Exemption for Renovation N. C. Gen. Stat. § 131E-184 (g) and
Request for Confirmation of Material Compliance
Renovation and Expansion at the Main Campus of Triangle Orthopaedic Surgery Center, Wake County, CON Project ID # J-8616-10, FID # 101146

Dear Ms. Frisone:

Please accept this letter as prior written notice pursuant to N. C. Gen. Stat. § 131E-184 (g) that Triangle Orthopaedic Surgery Center ("TOSC") intends to renovate and expand a portion of its existing ambulatory surgical facility in Wake County. Also, this letter requests confirmation from the Healthcare Planning and Certificate of Need Section that the development of two procedure rooms at TOSC is in material compliance with the Certificate of Need issued for the project.

Overview

In accordance with N. C. Gen. Stat. § 131E-184 (g), the sole purpose of the project is to renovate and expand a portion of the existing health service facility on the main campus of TOSC. The project site is the main building of TOSC. The facility plan for the project is included in Exhibit 1 that shows the areas of renovation and expansion.

Located at 7921 ACC Boulevard, Raleigh, TOSC opened its doors in February 2013 as an Ambulatory Surgery Demonstration project. This is the main campus location of the health service facility where TOSC provides clinical services. A copy of the 2019 License Renewal Application is included in Exhibit 2. Christine Washick, RN, CASC, is the Administrator and her office is located in the TOSC main buiding . Her role includes the exercise of adminstrative and financial control of the licensed ambulatory surgical facility. TOSC adminstration, finance and medical records departments are located on the first floor of the facility.

No change in the licensed beds or licensed operating room capacity at TOSC will result from the expansion and renovation project. The project does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

P(919)596-8524 7921 ACC Boulevard Raleigh, NC 27617 F(919)596-6640

www.triangleorthosurgerycenter.com

New Construction and Renovations

As seen in the attached plan in Exhibit 1, the project involves 5,320 square feet of new construction and renovations of 1,930 square feet at the TOSC main building. New construction will increase the facility capacity with two unlicensed procedure rooms to serve less complex surgical cases. This will enable TOSC to enhance staff productivity and reduce the frequency of having to extend hours of surgery. The three additional pre-operative bays will increase productivity and improve patient flow. Two extended stay recovery rooms will allow the facility to provide greater comfort and privacy to patients that have more complex surgery and may require extended recovery times. Renovations will expand waiting area capacity and improve workflow in the business office and reception area and employee support areas. Site improvement plans include the site work for the facility expansion and include an elevated walkway to access parking areas ajacent to the property.

Total Project Capital Cost

The total project capital cost for the TOSC renovation and expansion is approximately $4 million and includes all renovations and construction costs, site work, architect fees, contingency, furniture and equipment. The TOSC project does not include any of the major medical equipment that would require certificate need approval.

Historical Certificate of Need Compliance Reporting and Future Material Compliance

Renovation and expansion plans are timely because TOSC has completed five years of compliance reporting and fulfilled its responsibilities in conformance with its Certificate of Need Conditions as an Ambulatory Surgery Center Demonstration Project. As seen in Exhibit 2, the TOSC 2019 License Renewal Application documents that the facility is licensed and accredited with high utilization of its two licensed operating rooms. In Exhibit 3, the letter from Project Analyst Michael J. McKillip documents that the development of Triangle Orthopaedics Surgery Center CON Project ID# J-8616-10 was completed on April 16, 2018.

TOSC requests that the Healthcare Planning and Certificate of Need Section provide written confirmation that the development of two procedure rooms at TOSC is in material compliance with the Certificate of Need issued for the project that is included in Exhibit 4. The justification for this request is outlined as follows:

1. The Division of Health Service Regulation has previously determined that the development of procedure rooms in licensed healthcare facilities is not regulated by Certificate of Need.
2. Exemptions from Certificate of Need have previously been issued by the Agency for the development of procedure rooms in ambulatory surgical facilities and hospitals.
3. The development of TOSC as a single-specialty ASC demonstration projection was deemed complete on April 16, 2018 with five previous years of compliance reporting.
4. TOSC is committed to materially comply with the applicable Certificate of Need conditions still remaining on the certificate for CON Project ID# J-8616-10.
5. TOSC agrees that procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.

Thank you for your consideration of this request. Please feel free to contact me at (919) 596-8524 if you have any questions or need additional information.

Sincerely,

Christine Washick, RN, CASC
Administrator

Attachment: Exhibits 1 to 4

EXHIBIT J

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Acute and Home Care Licensure and Certification Section
Regular Mail: 1205 Umstead Drive
2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Overnight UPS and FedEx only: 1205 Umstead Drive
Raleigh, North Carolina 27603
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # Medicare #
_____
FID #:
PC _____ Date _____

License Fee: _____

2022
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant:
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: _____
Other: _____
Other: _____

Facility Mailing Address: Street/P.O. Box: _____

City: _____, State: _____ Zip: _____

Facility Site Address: Street: _____
City: _____, State: _____ Zip: _____
County:
Telephone: (___) _____
Fax: (___) _____

Administrator/Director: _____
Title: _____
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: _____ **Title**: _____
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive E-Mail: _____

Name of the person to contact for any questions regarding this form:

Name: _____ **Telephone**: _____

E-Mail: _____

9. Surgical Operating Rooms, Procedure Rooms, Gastrointestinal Endoscopy Rooms, Surgical and Non-Surgical Cases and Procedures

NOTE: If this License includes more than one campus, please copy pages 11-13 (through Section 9-g) for each site. Submit the Cumulative Totals and submit a duplicate of pages 11-13 for each campus.

Campus – *if multiple sites*: _____

a) Surgical Operating Rooms

A Surgical Operating Room is defined as a room "used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room" (G.S. §131E-146(1c)). These surgical operating rooms include rooms located in both Obstetrics and surgical suites.

Type of Room	Number of Rooms
Dedicated Open Heart Surgery	
Dedicated C-Section	
Other Dedicated Inpatient Surgery ***(Do not include dedicated Open Heart or C-Section rooms)***	
Dedicated Ambulatory Surgery	
Shared - Inpatient / Ambulatory Surgery	
Total of Surgical Operating Rooms	

Of the **Total of Surgical Operating Rooms**, above, how many are equipped with advanced medical imaging devices (excluding mobile C-arms) or radiation equipment for the performance of endovascular, cardiovascular, neuro-interventional procedures, and/or intraoperative cancer treatments? Your facility may or may not refer to such rooms as "hybrid ORs."	

b) Gastrointestinal Endoscopy Rooms, Procedures, and Cases

Report the number of Gastrointestinal Endoscopy rooms and the Endoscopy cases and procedures performed during the reporting period, **in GI Endoscopy Rooms and in any other location.**

Total Number of Licensed Gastrointestinal Endoscopy Rooms: _____

GI Endoscopies*	PROCEDURES		CASES		TOTAL CASES
	Inpatient	Outpatient	Inpatient	Outpatient	
Performed in Licensed GI Endoscopy Rooms					
NOT Performed in Licensed GI Endoscopy Rooms					
TOTAL CASES –must match total reported on Page 27 (Patient Origin – GI Endoscopy Cases) →					

*As defined in 10A NCAC 14C .3901 " 'Gastrointestinal (GI) endoscopy procedure' means a single procedure, identified by CPT code or [ICD-10-PCS] procedure code, performed on a patient during a single visit to the facility for diagnostic or therapeutic purposes."

c) Procedure Rooms (Excluding Operating Rooms and Gastrointestinal Endoscopy Rooms)

Report rooms, which are not licensed as operating rooms or GI endoscopy rooms, but that are used for performance of surgical procedures other than Gastrointestinal Endoscopy procedures.

Total Number of Procedure Rooms: _____

Campus – *if multiple sites*: _____

d) Non-Surgical Cases by Category

Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category - the total number of non-surgical cases is an unduplicated count of non-surgical cases. **Count all non-surgical cases, including cases receiving services in operating rooms or in any other location.**

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Endoscopies OTHER THAN GI Endoscopies		
Performed in Licensed GI Endoscopy Rooms		
NOT Performed in Licensed GI Endoscopy Rooms		
Other Non-Surgical Cases		
Pain Management		
Cystoscopy		
YAG Laser		
Other (specify)		

e) Surgical Cases by Specialty Area

Enter the number of surgical cases performed in licensed operating rooms only, by surgical specialty area. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area – the total number of surgical cases is an unduplicated count of surgical cases. **Count all surgical cases performed only in licensed operating rooms. The total number of surgical cases should match the total number of patients listed in the Patient Origin Tables on pages 28 and 29.**

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 8.(a) 4. on page 9)		
General Surgery		
Neurosurgery		
Obstetrics and GYN (excluding C-Sections)		
Ophthalmology		
Oral Surgery/Dental		
Orthopedics		
Otolaryngology		
Plastic Surgery		
Podiatry		
Urology		
Vascular		
Other Surgeries (specify)		
Number of C-Sections Performed in Dedicated C-Section ORs		
Number of C-Sections Performed in Other ORs		
Total Surgical Cases Performed Only in Licensed ORs		

f) Number of surgical procedures performed in unlicensed Procedure Rooms: _____

EXHIBIT K

In the Matter Of:

Rex Hospital v North Carolina

Michael John Mckillip

June 09, 2020

934 Glenwood Ave SE
Suite 250
Atlanta, GA 30316
855.478.7376

STATE OF NORTH CAROLINA IN THE OFFICE OF ADMINISTRATIVE HEARINGS

COUNTY OF WAKE

REX HOSPITAL, INC., Petitioner, v. NC DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTH CARE PLANNING and CERTIFICATE OF NEED, Respondent, And WAKEMED, DUKE UNIVERSITY HEALTH SYSTEM INC., TRIANGLE ORTHOPAEDICS SURGERY CENTER LLC, WAKE SPINE AND SPECIALTY SURGERY CENTER LLC, Respondent-Intervenors.	20 DHR 00889
WAKEMED, Petitioner, v. NC DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTH CARE PLANNING and CERTIFICATE OF NEED, Respondent, And REX HOSPITAL, INC., DUKE UNIVERSITY HEALTH SYSTEM INC., TRIANGLE ORTHOPAEDICS SURGERY CENTER LLC, WAKE SPINE AND SPECIALTY SURGERY CENTER LLC, Respondent-Intervenors.	20 DHR 00921

Deposition of MICHAEL JOHN McKILLIP

Volume 2

Remotely Given

Tuesday, June 9, 2020

Reported by: Karen K. Kidwell, RMR, CRR

(Caption continued on next page)

Page 250

Correct?
A. Yes.
Q. Okay. So let me direct you to the first sentence of the third paragraph, which says, "The CON project" -- so the project for which they're applying now. It says, "The CON project involves no new construction and no renovations to the facility." Do you see that?
A. Yes.
Q. So TOSC is -- it's the exact same construction that's proposed for both the procedure rooms and its application to add two more ORs, right?
A. Yes.
Q. Okay. And the only difference in the capital cost here that's discussed later in that same paragraph is a recommendation of a contingency budget of $250,000, right?
A. Yes.
Q. Okay. And that's not -- and that's because the -- the construction section has the authority to recommend changes based on licensure and regular requirements for operating rooms?
A. That's the reason they state, yes.
Q. Okay. Yes. So they're -- they're not -- the architect is not saying in this letter that

Page 251

construction section will impose any additional requirements, but just that they have the authority to, so they could. Right?
A. That's how it reads, yes.
Q. And the capital cost budget for this project also includes an equipment budget that starts on Bates page 457. I want to have you turn there, please.
A. Okay.
Q. Have you read this equipment cost letter and budget, which is on the following page, before, Mr. McKillip?
A. I don't recall at this time reading it.
Q. Okay. If you would, take a minute to read it, and just look up and let me know when you're done, please.
MR. HEWITT: I think I might be losing my connection now.
THE WITNESS: Okay.
BY MR. HEWITT:
Q. Okay. So let me direct your attention to the third paragraph of that equipment budget letter, Mr. McKillip. And the first paragraph -- or the first sentence of that paragraph, I'm not going to read it, because it's long, but it's saying that in

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addition to the costs identified by the architect, they're providing an initial $1.2 million estimate for a number of different items there. Do you see that sentence?
A. Yes.
Q. Okay. And do you see at the end of that sentence which -- where it says that the expenses -- well, sorry. It says -- it describes the "expenses that are related to both the CON-exempt project and the CON project application." Do you see that?
A. Yes.
Q. Okay. So do you understand that to mean that the expenses that are outlined on this equipment budget are related to both the exempt project to build two procedure rooms and also to the proposed project to develop ORs?
A. Yes, that seems to be what they're saying.
Q. Yeah. And the very next sentence says, "Therefore, TOSC document that the CON capital cost amount includes all capital costs related to both the CON-exempt project as well as to the CON project."
So it's the same -- it's the same costs, regardless of whether they're developing procedure rooms or ORs, isn't it?
MS. HEATH: Objection.

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THE WITNESS: Well, I'm just not sure it's -- if it includes both the costs being incurred for procedure rooms and the costs that will be incurred for operating rooms as a combined, and therefore, you know, only part of it would be incurred for the procedure rooms, if the operating rooms were not approved. But it just seems to be inclusive of everything.
BY MR. HEWITT:
Q. Right. Well, did they distinguish anything in their documentation of equipment that would be used for one of the projects but not the other?
A. No.
Q. Okay. And let me have you look at the actual line items on the equipment budget that's on Bates page 458. There are a whole bunch of them, but I want you to look at them.
Before you look at the list, but what my question is going to be is, would any of those expenditures have required TOSC to get a CON, if they had spent these amounts after developing procedure rooms?
A. No.
Q. Okay. So if they had just developed

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procedure rooms, they could have bought and equipped those procedure rooms with all of this equipment without ever having to get CON approval from the agency, right?

A. Correct.

MS. HEATH: Objection.

BY MR. HEWITT:

Q. So would you understand from the way the application is written that the two rooms are going to be built and equipped the same, regardless of whether they are developed as procedure rooms or operating rooms?

A. Well, I can't tell that, but it looks like they have budgeted for any eventuality, whether it's two procedure rooms or two operating rooms.

Q. Okay. But to -- to the first part of what you just said, which is you can't tell that, you can't tell from the application that there is going to be any difference at all in how these rooms are built or equipped, based on what they put in their application.

And what I mean, any difference between whether they're developed as ORs versus whether those same two rooms are developed as procedure rooms.

A. Correct.

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Q. And so you can't tell any difference from the application as to how they would be designed any differently if they were ORs versus procedure rooms, can you?

A. Correct.

Q. You can't tell any difference in how they would be constructed if they were ORs versus procedure rooms, can you?

A. No.

Q. And you can't tell any difference in how they would be equipped as procedure rooms versus operating rooms, can you?

A. No.

Q. Can you tell any difference in how they would be staffed, as procedure rooms versus operating rooms, from their application?

A. I don't recall a discussion of that in the application.

Q. Okay. Is there any respect in which you can tell that how these two rooms would be developed would be different if they're developed as ORs versus procedure rooms?

A. No.

Q. So now I want to have you turn -- well, before I have you look at other places in the

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application, let me ask you about the regulation of licensure -- excuse me, the regulation of procedure rooms versus licensed operating rooms.

Correct me if I'm wrong, but an ambulatory surgical facility, by definition, has to have at least one licensed operating room?

A. Yes.

Q. Okay. And let me have you look in the CON Act, which is also in the agency file. So if you would put the TOSC application aside for a few minutes. I'm in the CON Act, which starts on Bates 452 -- 451, rather, Mr. McKillip.

A. Okay.

Q. Just let me know when you get there. And let me have you turn to the definition of "operating room" under the CON Act, which is on Bates 460.

A. Okay.

Q. Could you do me a favor, please, and just read the definition of "operating room" into the record?

A. "18C, Operating room: A room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room."

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Q. Okay. I want to start an exhibit -- let's see here. Let me know when you can see it on the screen.

MR. HEWITT: Bethany, this is the one that I've marked as Exhibit Number 15.

(Exhibit 15 was marked for identification.)

MS. BURGON: Is it 16 or 15?

MR. HEWITT: I marked it as 15.

MS. BURGON: We got it.

MR. HEWITT: Okay.

BY MR. HEWITT:

Q. All right, Mr. McKillip, would you please -- before I move on to something else, I want to just have you compare the definition of "ambulatory surgical facility" -- and this is -- I've got to find the right page. Sorry.

It's on the second page of Exhibit Number 15. GS 131E-146, the definitions.

A. Okay.

Q. And so let -- let me back up. Exhibit Number 15, Mr. McKillip, do you -- would you recognize what starts on the second page of Exhibit Number 15 as Part 4, General Statutes, Chapter 131E, Article 6, which is the Ambulatory Surgical Facility Licensure Act?

A. Yes.
Q. Okay. Let me have you look at the "Definitions" section, which is Subsection 146 -- or Section 146, rather -- and the definition of "ambulatory surgical facility." Just take a minute to look at that.
Can you confirm for me that that is substantially the same definition that's used under the CON Act for ambulatory surgical facility?
MS. HEATH: Marc, are we looking at a definition as part of 131E-146?
MR. HEWITT: Yes, and comparing that against the --
MS. HEATH: Could you move the document to the next page, or the page where the operative language falls? Or is it on this page 35?
MR. HEWITT: The definition that I've asked Mr. McKillip to look at is on page 35.
MS. HEATH: Okay.
MR. HEWITT: It's 131E-146, Subsection (1).
MS. HEATH: I see. Thank you.
MR. HEWITT: Yes.
THE WITNESS: Yes, the definitions appear to be quite similar.

BY MR. HEWITT:
Q. Okay. And down to both those definitions, and ASF has to have at least one licensed OR, right?
A. Yes.
Q. Okay. Mr. McKillip, I'm going to ask you with respect to both the CON Act and also the ASF Licensure Act, but I want you to tell me whether or not there is a definition of "procedure room," or "minor procedure room," under either of those two Acts.
So let's start with the Ambulatory Surgical Facility Licensure Act, since we've already got that up on the screen. Can you tell me if there's a definition of "procedure room" or "minor procedure room" in -- in that statute?
MR. HEWITT: And Counsel, I'm happy to go to an individual page if you want, but I e-mailed a full copy of this exhibit to all counsel last night.
THE WITNESS: I do not see a definition for "procedure room."
BY MR. HEWITT:
Q. Okay. Is there a definition for "minor procedure room"?
A. No.

Q. Same question with respect to the CON Act, Mr. McKillip, which is in the agency file: Is there a definition for "procedure room" or "minor procedure room"?
A. No.
MS. BURGON: Hey, Marc, when you get to a good point for a break, I think probably we can all use one, but when you finish up your line of questioning.
MR. HEWITT: Certainly. I think I'm pretty close to that anyway.
BY MR. HEWITT:
Q. Mr. McKillip, to your knowledge, is there anything in the CON Act that would differentiate what a procedure room is versus what an operating room is?
A. No.
Q. Same question with respect to the ASF Licensure Act: Is there anything in that Act that would differentiate an operating room from a procedure room?
A. I have not read the entire Act, but I don't see anything.
Q. Okay. Just based on your general experience and knowledge, are you aware of any such distinction?

A. No.
MR. HEWITT: Now is as good a time as any to take a break. Do you want to go ten minutes?
MS. BURGON: Great. That would be great. Thank you.
MR. HEWITT: Okay. Start back up at 11:00. Thank you.
(A recess transpired from 10:50 a.m. until 11:02 a.m.)
(Exhibit 16 was marked for identification.)
MR. HEWITT: Back on the record.
BY MR. HEWITT:
Q. Mr. McKillip, let me have you now take a look at Exhibit Number 16, which I believe is up on screen.
MR. HEWITT: Bethany, can you see Exhibit 16 on screen?
MS. BURGON: I can. It's hard -- it's the same as the hard copy I've given the client.
BY MR. HEWITT:
Q. It is. Let me see if I can get a little bit easier to read on screen. Okay.
All right. Mr. McKillip, are you familiar with what Exhibit Number 16 is?
A. Well, I know what it is, but I've not read

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it.
Q. Okay. What is it?
A. It's Subchapter 13C, Licensing of Ambulatory Surgical Facilities.
Q. Okay. So these are the administrative rules for the licensure of ASCs or ASFs?
A. Yes.
Q. All right. Is there a definition of "operating room" in these rules?
A. Yes.
Q. All right. Is that at the top of the second page?
A. Yes.
Q. Okay. And you see there the definition of "operating room" reads, "a room in which surgical procedures are performed"?
A. Yes.
Q. Is there a definition -- is there a definition of "procedure room" under the ASF licensure rules?
Mr. McKillip, did you hear my question?
A. I did. The answer is no.
Q. Oh, I'm sorry. If you answered, I didn't hear you.
Let me direct your attention to -- well,

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are you aware of whether there's any distinction between operating rooms and procedure rooms under the ASF licensure rules?
A. Well, I have not read these rules.
Q. Okay. To your general knowledge, is there any such distinction in the licensure rules?
A. I'm not aware of any.
Q. Okay. Let me have you look at the definition of "surgical suite," which is on the second page of the licensure rules. It's Section 10A NCAC 13C .0103, Subsection 28.
Can you just read that definition into the record, please.
A. I'm sorry. What's the reference again?
Q. It's Section 0103, the "Definitions" section, Subsection 28.
A. "Surgical suite means an area that includes one or more operating rooms and one or more recovery rooms."
Q. Okay. Does that definition appear to limit what can be in a surgical suite to only operating rooms and recovery rooms?
A. No.
Q. Okay. So isn't it correct that surgical suites can also include procedure rooms?

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A. Yes.
Q. And if you will take a look at Section .1100 of the licensure rules, "Surgical Facilities and Equipment." It will take me a minute to scroll there.
There we go. It's on page 12 of the Exhibit, Section .1100.
A. Okay.
Q. All right. Do you see there that under Section 13C .1101, the operating suite is required to have specific equipment under that rule?
A. Yes.
Q. Okay. That rule does not require specific equipment in operating rooms, does it? It speaks to specific equipment required in surgical suites?
A. Yes.
Q. And Section .1102 immediately below there, where it refers to "Care of Operating Suite," that again isn't specific to operating rooms, is it?
A. Correct.
Q. Okay. So both of those rules, if there are procedure rooms included in the surgical suite, then those rules would equal -- those rules would equally apply to the procedure rooms, just like they would for operating rooms, wouldn't they?

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A. I would think so.
Q. Now, you can -- I'm not going to -- I don't think I'm going to come back to those licensure rules for the time being, so you can put those aside if you like, Mr. McKillip.
Does -- I want to ask a few questions about DHHS, and whether DHHS and how DHHS regulates procedure rooms. And I first want to address the CON section or the -- you know, Health Planning and Certificate of Need section.
First of all, how does CON regulate procedure rooms?
MS. HEATH: Objection to this. And I can just have a standing objection, to the extent these questions are calling for a legal conclusion.
THE WITNESS: Well, development of procedure rooms are not considered a new institutional health service under the statute. So applicants, in my experience, can develop them without a Certificate of Need through -- just by obtaining an exemption letter.
BY MR. HEWITT:
Q. All right. And does the CON section limit the extent or limit the way in which a procedure room

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is constructed or equipped?
A. Not to my knowledge.
Q. Okay. Does the CON law or the CON regulatory scheme limit the way in which a procedure room is staffed?
A. Not to my knowledge.
Q. Now I want to ask a couple questions about licensure and certification. Does -- to your knowledge, does licensure and certification limit the way in which procedure rooms are built or equipped?
A. I'm not familiar with the requirements under licensure and certification.
Q. Okay. Do you have any knowledge of any limits placed on the development -- or the construction or equipping of procedure rooms by licensure and certification?
A. I do not.
(Exhibit 17 was marked for identification.)
BY MR. HEWITT:
Q. Let me have you look in the -- sorry, I think I've got my exhibits labeled a little bit the wrong way. Give me just a moment, please.
MR. HEWITT: All right. I apologize. I thought I had uploaded one that I do not appear to have uploaded, but give me a second. I've

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got it. I know I uploaded it to the shared documents. I just need to share it with all of you guys.
And I have not marked this one in the title. I had marked a different exhibit, thinking it was the same one, but it's not. Give me just a moment.
Okay. Let me know when you all can see that. There's a letter on DHHS letterhead that should appear on screen.
THE WITNESS: Okay.
MR. HEWITT: Let's go off the record for just a moment.
(A recess transpired from 11:12 a.m. until 11:15 a.m.)
(Exhibit 18 was marked for identification.)
BY MR. HEWITT:
Q. Do you recognize what Exhibit Number 18 is?
A. Yes.
Q. Okay. What is it?
A. It's an exemption letter, or determination given to North Carolina Specialty Hospital in June of 2017 for renovation and expansion of their facility.
Q. All right. Have you previously seen this

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exemption letter before today?
A. No.
Q. All right. I want to ask some questions about it, and I can go wherever in the document.
I apologize for the inconvenience. I thought I had sent it over ahead of time, and I just made a mistake. But I want to ask you some questions about what it authorizes the applicant in that case to do. So anywhere you need me to go in the document for you to be able to verify that, please let me know, and I'll try to -- to get to the right places.
But my questions -- do you understand this to be an exemption that was granted to North Carolina Specialty Hospital in 2017?
A. Yes.
Q. Okay. And do you understand that this allowed that entity to expand -- among other things, it was allowed to expand the procedure room that was in its operating room suite in its ambulatory -- or in its facility?
A. Yes.
Q. And also to develop another procedure room in its operating room suite?
A. Yes.
Q. And so would you agree with me, as a

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general proposition, that operating room suites or surgical suites can include procedure rooms in addition to operating rooms?
A. Yes.
Q. All right. And would you agree with me that the exemption that was granted was granted under GS 131E-184G?
A. Yes.
Q. And that's the same exemption that allowed TOSC to add two procedure rooms to its existing facility that they got in May of 2019, isn't it?
A. Correct.
Q. And I want to scroll down to the last page. It's an attachment. And this is a letter that's dated November 27th, 2012. If you would just take a moment, and let me know when you've had a chance to look over that letter, Mr. McKillip.
A. Okay.
Q. Have you seen this letter from Mr. Pratt before, Mr. McKillip?
A. I think I have.
Q. Okay. Is this -- is this consistent with your understanding of the CON sections? I don't know whether "policy" is the right word, but the CON sections' practice of not regulating the development

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of procedure rooms?
A. Yes.
Q. And so what Mr. Pratt's letter says, in part, is that DHHS will only regulate procedure rooms to the extent of making sure that they comply with the Federal Life Safety Code, as referenced in the North Carolina Administrative Code; is that correct?
A. Yes.
Q. Okay. Isn't it true that the Federal Life Safety Code is a National Fire Protection Association standard?
A. I don't know.
Q. Okay. Well, let me have you look quickly back at Exhibit 16. And I want to get -- I have to find the right rule. Give me just a moment. I'm looking for section -- and under the "Physical Plant Construction" section of the rules.
Mr. McKillip, I don't know if you can see it on screen, but Exhibit 16, on page 14, the section on "Physical Plant Construction"? Scrolling down to Section .1402, the Subsection (b)(2).
I'll try to zoom in a little bit more whose those of us like me whose vision is not great. But in Subsection 1402(b)(2), includes the language: "The following National Fire Protection Association

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standards, codes, and guidelines" are one -- among -- incorporated into the licensure rules. And Subsection (e) refers to the Life Safety Code. Do you see that?
A. Yes.
Q. Okay. So is it your understanding that the Federal Life Safety Code that's referred to in Mr. Pratt's letter, that is incorporated into the North Carolina Administrative Code, is this National Fire Protection Association minimum standard?
A. Yes.
Q. All right. So I'm going to jump back to Mr. Pratt's letter in Exhibit Number 18. And is it your understanding that DHHS only regulates procedure rooms to the extent of making sure that procedure rooms comply with that fire protection standard that's incorporated into the North Carolina Administrative Code?
A. That looks like what the letter is saying.
Q. Okay. And so I guess if TOSC in -- in this context, or the context of this case, if TOSC wants to build -- let me back up and start that question over again.
If TOSC wants to build two procedure rooms that are identical to their existing operating

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rooms -- not the ones they've applied for, but their existing operating rooms that they already have -- if they want to build two procedure rooms that are identical to those existing operating rooms, they can do that without making them ORs, or without having to get a CON for ORs, can't they?
A. That is my understanding.
Q. Right now, the procedure rooms that are currently in development at the existing TOSC facility, those are expected to be complete by November of 2020, as represented in their CON application, right?
A. Correct.
Q. All right. Let me briefly have you look at the exhibit number -- it's the TOSC application, the facility plan, which I think is in Exhibit K1 in the TOSC application.
A. Okay.
Q. Let me find the page for you.
No, I'm sorry, I sent you to the wrong exhibit.
What I'm actually interested in is the way that they propose their procedure rooms. So it's in the exemption that they got previously, so it is Bates 160.

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A. Okay.
Q. Do you know where the procedure rooms are versus the existing operating room on that page, Mr. McKillip?
A. It's difficult to read, but I think so.
Q. All right. If you are looking at -- that page is printed in land -- well, it's printed portrait, but if you turn it so that the words "Schematic Plan" are upright to you, would you understand that the two proposed procedure rooms for that exemption are in the lower left corner?
A. Correct.
Q. All right. And moving directly to the right from those two rooms, there's one room that -- the one room immediately adjacent that has an interior wall is not the one that I'm referring you to; but there are two rooms immediately to the right of that. Do you -- do you understand that those two rooms are their existing two operating rooms?
A. Yes.
Q. Okay. Does it appear to you that the procedure rooms that are proposed in this exemption request are as big or at least as big as their existing operating rooms?
A. It would appear so.

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Q. Okay. If you compared that plan to the design of the operating -- well, I'm not going to do that. We've already verified the means of construction that was proposed.

But do you see any difference in the proposed layout of the procedure rooms that they had proposed compared with the existing two operating rooms?

A. No.

Q. All right. And then finally, let me have you look back at page -- Bates page 28 at the -- of the TOSC application.

A. Okay.

Q. Okay. And so under "Demonstration of Need," Question 4 in Section C, in the middle of the paragraph, there's a sentence that reads, "The two operating rooms will be developed in facility spaces that are currently being developed as procedure rooms." Do you see that?

A. No. What -- what page are we on?

Q. Bates page 28. It's in Section C. It's right under the heading "Demonstration of Need." Question 4A.

A. Okay.

Q. Middle of the paragraph, the sentence

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reads, "These two operating rooms will be developed in facility spaces that are currently being developed as procedure rooms."

A. Yes.

Q. Do you see that? Okay.

So would -- is it your understanding that TOSC is already in the process of building these two rooms? Right?

A. Yes.

Q. Okay. And if TOSC -- TOSC has now applied for a CON to develop these two rooms as operating rooms, correct?

A. Yes.

Q. Okay. But if they don't get the CON, they're going to develop them anyway. They're just not going to call them operating rooms. Right?

A. Correct.

Q. And surgery can be done in procedure rooms. I think we already covered that. Isn't that right?

A. Yes.

Q. And in the TOSC application, let me actually point you to Bates page 191, which I think is their most recent licensure renewal application. Well, the licensure application actually starts on

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Bates page 185, but let me refer you to Bates page 191.

A. Okay.

Q. Actually, it's 192. Forgive me. If you will turn over onto the reporting form.

A. Okay.

Q. And so one of the -- I just want to particularly point your attention to subpart B of the question on Bates page 192, where it asks the licensed ASF to report the number of surgical procedures that are performed in unlicensed procedure rooms. You see that?

A. Yes.

Q. Okay. So that's part of the licensure -- renewal application for all ASCs, right?

A. Correct.

Q. And obviously TOSC doesn't have anything to report in that particular application, because it currently doesn't have -- at the time, at least, it didn't have any procedure rooms?

A. Correct.

Q. All right. But DHHS recognizes that procedure rooms are open for surgical procedures?

A. Yes.

Q. Do payors require that certain procedures

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that can be done in an ASC can only be done in a licensed operating room?

A. I don't know.

Q. Does the TOSC application represent that any payor requires that certain procedures can only be done in a licensed OR?

A. I don't recall that discussion at this time.

Q. To your knowledge, does CMS -- Centers for Medicare and Medicaid Services -- does CMS require that ambulatory surgery cases, that any particular ambulatory surgery cases can only be done in a licensed operating room?

A. I know that CMS has a list of procedures that they will pay for in various settings. I'm not sure if that's the same thing that you're referring to.

Q. Well, yeah, it is. Isn't it true that CMS has a list of procedures for which it will reimburse in an ambulatory surgical center setting?

A. Yes.

Q. Okay. And they also have -- well, let me back up a step. CMS has a hospital outpatient prospective payment system, doesn't it?

A. I'm not familiar with all the hospital

EXHIBIT L

Petition to the State Health Coordinating Council
Regarding Special Need Single Specialty ASC for Vascular Access
for Nash County
2023 State Medical Facilities Plan

July 27, 2022

Petitioner:		*Contact:*	
Name:	Carolina Vascular Care, PLLC	**Name:**	Karn Gupta, MD
Address:	PO Box 1276 Morrisville, NC - 27560	**E-mail:**	Karn Gupta<guptakarn@gmail.com>
		Phone:	252-220-5470

STATEMENT OF REQUESTED ADJUSTMENT

Carolina Vascular Care, PLLC requests the following change to the *2023 State Medical Facilities Plan* (*SMFP*) to address a special need for a single specialty ambulatory surgical center dedicated to vascular access in Nash County:

> *There is a special need in Nash County for one operating room that can only be located in an ambulatory surgical center dedicated to vascular access procedures.*

REASONS FOR THE PROPOSED ADJUSTMENT

Overview

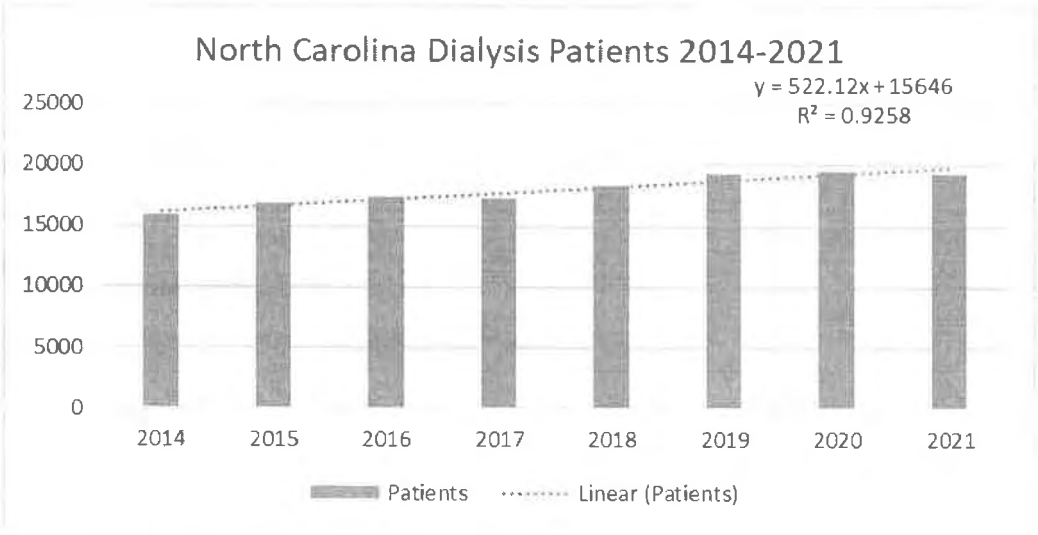
A critical element of dialysis care involves frequent maintenance of the access point for the dialysis procedure. Very few nephrologists in this state are trained and experienced to do these procedures. Today, the procedures are most efficient and cost-effective when done in a vascular access ambulatory surgery center. There are only two of these in North Carolina, one in Raleigh and one in Charlotte. A five-county area around Rocky Mount has more than enough dialysis patients to support one in Rocky Mount, but there is no need in the Proposed 2023 State Medical Facilities Plan ("SMFP") that would enable its development. The five counties are Nash, Edgecombe, Halifax, Northampton, and Wilson.

Importance of Vascular Access in Dialysis Care

Approximately 1 in 7 US adults have some level of chronic kidney disease (Chronic Kidney Disease in the United States, 2021). This often progresses to complete kidney failure – i.e., End Stage Renal Disease ("ESRD") (CKD Related Health Problems, 2021). According to data in the NCHSR Dialysis Patient Origin

reports, approximately 19,000 North Carolina residents were on renal dialysis in 2021 and their numbers are steadily increasing (NCHSR, 2021).

Figure 1 – North Carolina Dialysis Patients, 2014-2021



Source: (NCHSR, 2021)

These individuals must have either dialysis or a kidney transplant to survive. They require hemodialysis every other day in order to filter their blood through a machine that removes waste products. Connection to the machine requires the person to have a vascular access point. Vascular access, including an arteriovenous ("AV") fistula or graft, provides direct access to the individual's circulatory system, so the dialysis machine can remove, filter, and return clean blood back to the person. While indispensable to hemodialysis treatment, because they are artificial and are subject to unnatural high blood flows during the dialysis treatment, even the best vascular access points have high dysfunction rates (Grapsa, 2012).

When the access point becomes dysfunctional, patients are susceptible to clotting, infection, and venous injury. Therefore, dialysis access point management, and treatment of vascular access complications are critical to an ESRD patient's successful treatment program. When the access point gets compromised, ESRD patients cannot receive dialysis. They need immediate repair; because, without dialysis they risk hospitalization, serious complications, and death (World Kidney Day).

Vascular Access Clinical Options

Vascular accesses are surgically created vein and artery blood shunts that fall into three categories (see Attachment A):

- Catheters
- Arteriovenous (AV) Grafts or
- Arteriovenous (AV) Fistulas

Catheters and AV Grafts are synthetic shunts, whereas AV fistulas are constructed from the patient's own veins and arteries. Catheters are typically the first access a dialysis patient will receive because catheters allow immediate access, whereas AV grafts and AV fistulas require anywhere from three to six months post-surgery to mature into functioning accesses. Despite the maturation period, AV grafts and AV fistulas are preferable to catheters because catheters have the highest infection rates among the three. Catheters have a 20 percent infection rate, AV grafts a 10 percent infection rate, and AV fistulas a 0.5 percent infection rate. All vascular accesses are susceptible to some dysfunction. As **a result, the average dialysis patient requires two to four access interventions per year** to maintain a well-functioning access (Lok, 2019) (Wong SPY, 2022).

For ESRD patients on hemodialysis, vascular access is a **lifeline** – but one that requires regular attention. Without a functioning vascular access, patients cannot receive hemodialysis; a dialysis delay of even two days can mean life-threatening complications and death.

Vascular Access Settings

Today, vascular access procedures are offered in three settings: hospitals (HOPD), ambulatory surgery centers (ASC) and physician offices. Medicare and Medicaid set the framework and third-party insurance programs follow. There are different payment rate schedules for each setting. The physician office setting is often referred to as an Office Based Laboratory ("OBL") and is classified as an "Extension of Practice."

Eastern North Carolina has no health facility that offers vascular access procedures in an ambulatory surgical setting. The nearest is in Raleigh. In HSA VI, the geographic region around Nash County now has enough renal dialysis patients to support a vascular access care ambulatory surgery center. The following paragraphs will provide more information.

SMFP Operating Room Methodology and Vascular Access Centers

North Carolina licenses operating rooms in two places: hospitals, and ambulatory surgical centers ("ASC"). Certificate of Need governs the number of operating rooms. Physician offices cannot have operating rooms in North Carolina. In North Carolina, with the exception of GI endoscopy centers, an ASC license requires at least one operating room.

The number of operating rooms is determined by the SHCC using a standard methodology for calculating operating room need by service area. Three of the five counties, Nash, Edgecombe, and Wilson are single county service areas. Halifax/Northampton is a two-county service area.

In the Proposed 2023 SMFP, according to the standard methodology, every existing operating room is a generic room. The underlying and unstated assumption is that every operating room has the same capabilities. Alternately, it assumes that the mathematics will balance out the few specialty operating rooms in each service area. Because of this, the standard methodology will only generate need for generic operating rooms. In large service areas, there will be sufficient operating supply to permit approval of a specialized facility dedicated to vascular access. Mathematically, this will not occur in small service areas like those included in this proposal. However, there are small geographies, like the one centered around Nash County, that can support a specialized vascular access center. Nash is already a specialty center for other services. It has a significant complement of nephrologists.

Although 90 percent of Nash County's ESRD residents receive dialysis in Nash County, according to the Table of Dialysis Data by County of Patient Origin, there is no option for them to maintain their vascular access in a freestanding outpatient setting (See Table 6B) (NC Dept of Health and Human Services, Division of Health Service Regulation, 2022). Most go to Raleigh for maintenance of their access.

The same is true for the ESRD patients from Northampton, Halifax, Edgecombe, and Wilson County. These counties have dialysis centers, but do not have a freestanding vascular access surgical center.

The 2023 Proposed SMFP shows no need for additional operating rooms in any county in NC. It shows a surplus of 5.21 operating rooms in Nash County and a surplus of 4.05 operating rooms in the Halifax/Northampton County group. By extension, without a Special Need in the 2023 SMFP, there is no way for anyone other than the hospitals to initiate a new vascular access ASC in Nash, Halifax, or Northampton in 2023, and the hospitals have shown no interest. This is not surprising. Vascular access maintenance requires more than a physical facility. It requires a trained, skilled vascular access nephrologist or a vascular surgeon who regularly performs the procedures, and a specialized support staff.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

ESRD patients from Nash and surrounding areas have a low baseline state of health. The nearest vascular access ASC is in Raleigh. These patients must travel 60 to 90 miles for routine or emergent vascular access care. As many as one in five is dually eligible for Medicaid. For most, resources are limited, and most have underlying chronic diseases like hypertension and diabetes.

With no vascular access surgery center in Nash or the other four counties, ESRD residents have three choices: go to the emergency room, travel 60 to 90 miles, or do nothing. Most choose the first two options. Both require transportation assistance because the procedures involve sedation and driving is prohibited after the procedure. The do-nothing option can result in death when the dialysis provider can no longer attain access for lifesaving dialysis. The ER option will likely result in long wait times, hospital admission, and insertion of a catheter. Though better than imminent death, the catheter solution welcomes infection because it is an external connection to the heart. Many choose to travel, but as North Carolina population increases, so does road congestion and this option becomes less and less attractive to the older and frail ESRD patient population. Vascular access procedures are outpatient, which means patient copayment is required. Thus, for a service that may be needed the service every three months, the lower cost at a freestanding ASC is important. Not every Medicare patient will have the supplemental insurance to cover the copayment. Those who have supplemental insurance risk paying higher premiums later because of the higher cost.

Numerous studies have shown that patients have better outcomes and get more timely and much cheaper care in outpatient vascular access facilities compared to hospitals. See Attachments B and C. Without a special need for one operating room in the 2023 SMFP, the patients in Nash County and surrounding areas would continue to face high medical costs associated with getting any vascular work done at the hospital. In 2021 there were at least 1,183 ESRD patients in Nash, Halifax, Edgecombe, Wilson, and Northampton Counties. They require these procedures about two to four times a year (Lok,

2019) (Wong SPY, 2022). At this frequency, patients and their support systems often give up, accepting untimely death over the inconvenience.

Table A – Estimated Dialysis Patients by County, 2021

County	2019	2020	2021
Nash	293	303	303
Northampton	98	94	98
Halifax	253	259	242
Edgecombe	247	264	279
Wilson	316	314	261
Total	**1207**	**1234**	**1183**

Source: Dialysis Data by County of Patient Origin **(NCHSR, 2021)**

Table B – Estimated Vascular Access Procedures by County 2021

County	2019	2020	2021
Nash	879	909	909
Northampton	294	282	294
Halifax	759	777	726
Edgecombe	741	792	837
Wilson	948	942	783
Total	**3621**	**3702**	**3549**

Source: Table A multiplied by an average of 3 procedures per patient per year

For this cluster of counties, Nash is an accessible location and a traditional referral center.

Frequently, the physicians performing access procedures in the local hospitals, including Nash, do not know the ESRD patients or their vascular access history well enough to decide the best possible treatment option for them. The only freestanding ASC in these counties; Wilson Surgery Center, closed in 2020. Moreover, the ambulatory surgery center approved for Wilson Regional Medical Center in 2021 does not propose to offer vascular access procedures.

According to MedPAC, nationally, 35 percent of ESRD patients covered by Medicare are African American (MedPAC, 2022). African Americans, Native Americans and Hispanic populations are genetically at higher risk for chronic kidney disease. It is important to note that most people with chronic kidney disease are not aware of it (Chronic Kidney Disease in the United States, 2021). That indicates that the number of beneficiaries is likely much lower than the number of people who potentially could become beneficiaries.

Nash, Edgecombe, Halifax, Northampton and Wilson counties have very high population of African American, Hispanic and Native American residents.

Figure 2 – North Carolina African American Residents, 2018

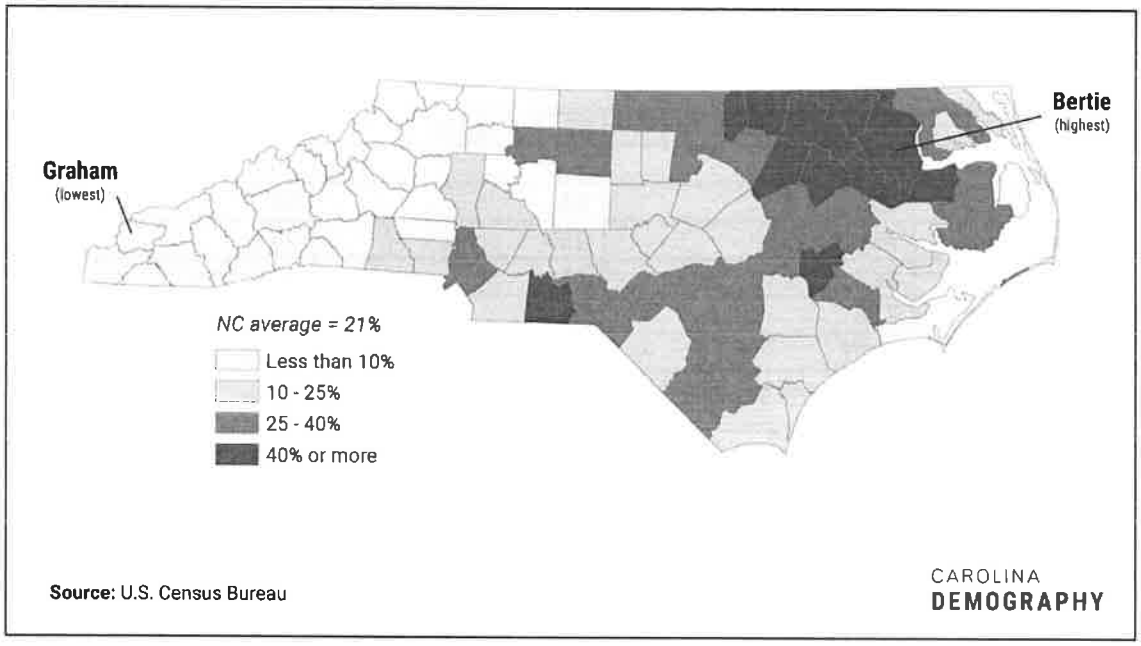


Figure 3 – North Carolina Hispanic Residents, 2018

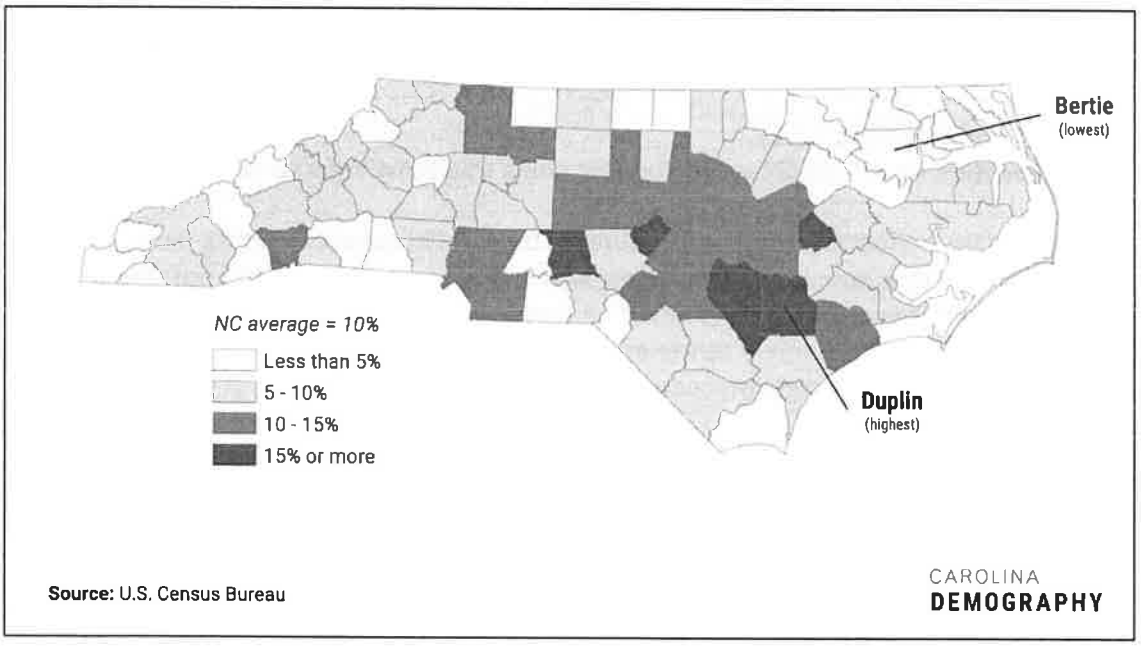
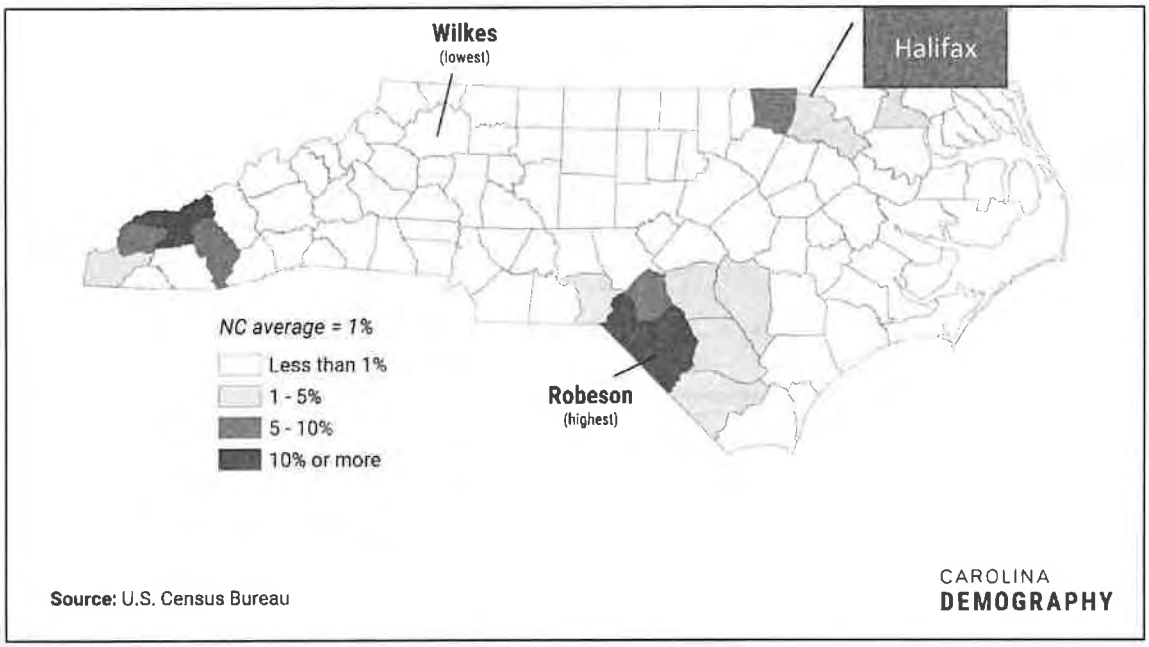


Figure 4 – North Carolina American Indian Residents, 2018



STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

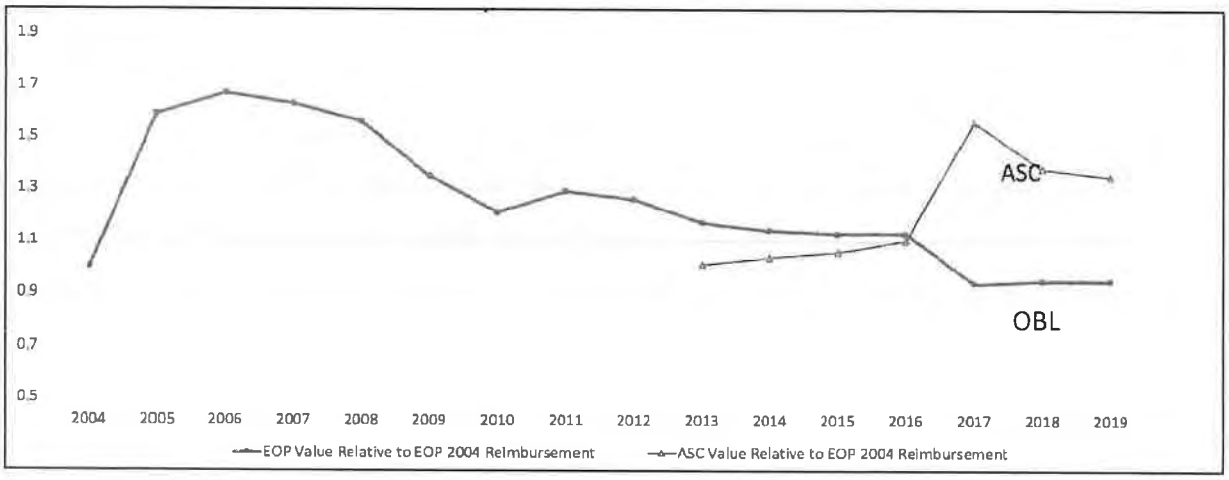
Provide an OBL in the Five-County Region

An OBL is a safe and practical location for providing vascular access procedures and for maintaining existing vascular access grafts. However, OBLs are at risk of extinction. In 2017, CMS began bundling codes and effectively reducing Medicare payment rates to OBLs.

Medicare is the primary payer for ESRD (Kirchoff, 2018). CMS has a different methodology for setting each rate. Medicare pays less for vascular access services provided in OBLs than in a hospital or ASC; and until recently, this was a satisfactory arrangement, with payment covering more than cost. The Medicare OBL payment reductions began in 2017 with a 39 percent cut and have escalated since then. In 2022, CMS instituted another 18 percent cut (Dialysis Vascular Access Coalition, 2021). More cuts are written into regulations for the next four years.

The following figure comparing OBL and ASC reimbursement rates for vascular access over time was developed by the American Society of Diagnostic and Interventional Nephrology (Litchfield, 2019).

Figure 5 – Reimbursement per Encounter Relative to 2004 OBL Rates



Source: Vascular access outpatient reimbursement trend **(Litchfield, 2019)**

CMS has announced plans to continue the reductions (Dialysis Vascular Access Coalition, 2021). CMS is pushing the OBL payment below OBL operating breakeven points. As this happens, OBLs will continue to disappear. The Dialysis Vascular Access Coalition is tracking the status of OBLs. Its website notes that more than 20 percent of respondents surveyed in 2018 stated that their centers had closed due to the cuts (Litchfield, 2019).

Carolina Vascular Care, PLLC has started planning for **an OBL (office-based lab)** in Nash County but unfortunately given the persistent reimbursement cuts from Medicare, this solution is not likely sustainable. Fixed operating expenses exceed income potential; 30 percent of all OBLs around the country have closed as reimbursement cuts continue the trend started in 2017 (Dialysis Vascular Access Coalition, 2021). The only way to keep a vascular access center open and functioning is to operate it as an ASC. Most patients, about 80 percent, are Medicare beneficiaries and the Medicare payment for the same procedure in an ASC is not overly generous, but it is enough to support operations. See Tables C and D.

Table C – OBL Comparison to ASC

CPT	Procedure Description	2022 Global Total Payments (Final)	2022 Pro + Facility (Final)	ASC - OBL	Variance %
36901	Fistualgram	$ 731	723	$ (8)	-1.1%
36902	Peripheral Angioplasty	$ 1,257	2,443	$ 1,186	94.3%
36903	Stent + Peripheral Angioplasty	$ 4,525	6,899	$ 2,374	52.5%
36904	Thrombectomy (no angioplasty)	$ 1,877	3,314	$ 1,437	76.6%
36905	Thrombectomy + Peripheral Angioplasty	$ 2,380	6,106	$ 3,726	156.6%
36906	Thrombectomy + Peripheral stent	$ 5,722	11,402	$ 5,680	99.3%
36907	Central Angioplasty	$ 613	143	$ 470)	-76.7%

Source: Data from CMS Final Physician Fee schedule 2022 https://www.cms.gov/medicare/physician-fee-schedule/search

Offer Vascular Access Procedures in Local Hospital Operating Rooms

Local hospitals have operating room capacity, but are not designed to respond to the unplanned, though non-emergent nature of dialysis vascular access procedures. Hospitals, by their nature, provide a broad scope of care. When performed in a hospital, even when the procedure is scheduled, vascular access cases are often delayed by other emergency cases (untimely); and are always much more expensive than when done in an ASC. Timely care is critical for ESRD patients because the access point is their lifeline. Because their staff is not trained in vascular access, hospitals often opt for the catheter option over the surgical AV shunt because every hospital with an ICU has staff trained to insert catheters. Data clearly associate this solution with shortened lives for the patients. Hospitals rely on staff at hand, and this is rarely an interventional nephrologist. Furthermore, owing to their competing responsibilities, hospital IR departments often only temporize an urgent or emergent clotted fistula or graft merely by placing a catheter, until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization and the deleterious sequelae of using a catheter for dialysis.

So why not do these procedures in the surplus operating room capacity at Nash General? There are many reasons, to name a few:

1. Since COVID, Nash has closed its day hospital where the focus was on outpatients alone. Now all surgery is done in the main hospital surgical suite.
2. Vascular access requires a special program with planned capacity for emergencies and a specialized staff that understands dialysis care. Nash has a hospital dialysis unit, and the necessary imaging equipment. Even that is not enough. The imaging equipment must be in the OR suite. Moreover, in the main hospital operating room suite, even the scheduled outpatient is at risk of getting delayed to accommodate a more urgent hospital patient. Please remember, a lot of these patients are diabetics who cannot fast for a prolonged time prior to their procedure. Also, an emergent patient will likely not be able to get accommodated for a same day procedure and would be at life threatening risks of missing dialysis. The dialysis center would have discovered the emergency but will be closed by the time he is discharged. That center, where

the patient gets regular treatment works on a tight schedule to stay efficient. It may not have an open slot the next day. So, the patient would have to wait two days for his routine slot at the dialysis center. There are no Sunday slots, so the delay could extend to three to five days. By then, the patient is retaining excess fluids, toxins and is at life-threatening risk.

3. These dialysis patients have weakened immune systems and are at high risk of infections and other complications in a hospital setting, risking patient safety. Large population-based studies have documented better outcomes across all measures for patients treated in freestanding centers compared to those treated in a hospital outpatient department. See Attachments B and C.
4. There is no vascular access specialist in Nash and surrounding counties. I have met with the clinical staff at Nash and with the local nephrology group. Nash is not organized to and does not provide this care. Staff told me they are excited that I would consider offering vascular access services in Rocky Mount. Unfortunately, as I mentioned, I cannot afford to offer these services in Nash without an ASC.
5. Based on insurance claims data, for the Rocky Mount zip code, the patient cost to get these procedures in the hospital outpatient department can be 5 to 6 times higher than in an ASC. For example, a routine angioplasty, which is the most common procedure for these patients, costs about $1,500 in an ASC compared to $8,000 in a hospital outpatient department, see Table D. Additionally, the patient would also be charged more for an anesthesia fee in a hospital setting. Because these are outpatient procedures, the patient must cover 20 percent of their medical bills which adds up significantly due to the frequent need for these procedures.

Table D – Reimbursements Rates for Vascular Access Procedures Based on Site of Service

CPT Code	Procedure	ASC	Hospital
36901	Fistulagram	596	957
36902	Peripheral Angioplasty	1,485	7,978
36903	Stent + Peripheral Angioplasty	1,240	5,042
36905	Thrombectomy + Peripheral Angioplasty	2,749	12,894

Source: https://www.fairhealthconsumer.org/medical/results , All prices are in-network and based on Rocky Mount zip code: 27804. Accessed 7/25/2022. This database is updated twice a year.

An interventional nephrologist knows the intricacies of ESRD and vascular access care, as well as other medical conditions that can affect vascular access. Although Carolina Vascular Care, PLLC is considering an OBL, that OBL will be only temporary unless it can procure a CON to become an ASC. Approved Medicare payment reductions will make the OBL unsustainable in the next few years.

Provide Vascular Access ASC in a Different Geography

As required of the summer petitions, this petition is focused on the geographic need in one part of the state. Carolina Vascular Care, PLLC has not investigated need in other geographies. What is clear to Carolina Vascular Care, PLLC is that the five-county region including Nash and surrounding counties needs its own vascular access ASC. Carolina Vascular Care, PLLC has studied this area and its patients and is advocating for the special needs of these patients.

Maintain the Status Quo

As demonstrated throughout this petition, the status quo already places a high travel burden on patients and puts them at the mercy of increasingly busy vascular access ambulatory surgery capacity in Raleigh. The local hospital option is at best, inefficient and expensive.

EVIDENCE OF NO UNNECESSARY DUPLICATION OF SERVICES

This proposed special need will not represent unnecessary duplication. Local hospitals do not want to offer this service, and it does not exist in this area. It would place a life-saving service closer to a large number of rural residents. As noted:

- There is no freestanding ASC in Nash, Halifax, Edgecombe, or Northampton Counties and the 2023 SMFP shows no need for an operating room that would be needed to permit a CON application for a center.
- No hospital has offered to joint venture its excess inventory and a joint venture would of itself increase the cost of initiating the center.
- With the exception of Wilson County, all surgery in these counties is hospital-based. In 2021, Wilson County was approved to develop a freestanding multi-specialty ASC however, that center did not include vascular access in its scope of proposed services.
- There are enough potential procedures and ESRD patients in the counties that relate to Nash to justify a vascular center – about 1200 patients and an estimated 3500 annual procedures (See Tables A and B).
- Patients and referring nephrologists have encouraged development of a vascular access ASC in Nash County (see Attachments D and E for speeches from SHCC public hearings).

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

Basic Governing Principles

1. *Safety and Quality*

This basic principle notes:

> *"...priority should be given to safety, followed by clinical outcomes, followed by satisfaction.*
>
> *"...As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area."*

Vascular access procedures are better for the patient when provided in a surgical setting that is subject to oversight. North Carolina licensure and CMS Certification bodies provide that quality regulation. OBLs are not subject to the same level of outside review.

Research also shows better clinical outcomes when vascular access procedures are done in a vascular access center rather than a hospital outpatient department. See Attachment B and C.

As demonstrated in the public hearing presentations by Mr. Robert Baggett (See Attachment D), patients are clearly more satisfied with the freestanding vascular access centers than with the hospital emergency rooms or outpatient department solutions.

2. *Access*

This basic principle notes:

> *"...The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.*
>
> *"...The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards."*

As noted in Table B, dialysis patients in Nash, Halifax, Edgecombe, Northampton, and Wilson counties, will need an estimated 3,500 procedures a year. Without a vascular access ASC, they will travel three hours or more for each procedure and an individual patient will make multiple trips a year. The life of a person on dialysis is already consumed by hours of routine weekly dialysis treatments. Denying this group better access is unreasonable.

Dialysis patients are not seeking vascular access care in their local hospitals because the local hospitals do not have the staffing and expertise required for ideal AV fistula and shunt procedures. The issue is not the institution's number of operating rooms, but the availability of the dedicated specialty vascular access care team.

3. *Value*

This basic principle notes:

> *"The SHCC defines health care value as the maximum health care benefit per dollar expended.*

"...Cost per unit of service is an appropriate metric...

"...At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit."

An OBL is less expensive than a surgery center, but existing and planned Medicare cuts will soon make this option unsustainable. The next least expensive setting is a single specialty ambulatory surgery center dedicated to vascular access. It is important that the special need specify dedication to vascular access. Otherwise, the Plan need could have the unintended consequence of producing a generic multi-specialty surgery center that would likely not be organized for the special emergency standby requirement of the renal dialysis patient.

Nash County and nearby communities have sufficient need to support a small, functional vascular access ASC with an efficient staff. Routine need is sufficient to provide a minimum of 1,312 hours of operating room care. Vascular access procedures take a minimum of 40 minutes each, this translates to approximately 1,968 procedures a year to achieve the 1,312 hours requirement. This is significantly less than the 3,500 procedures per year estimated in Table B. This is also more than it would take for the ASC to be financially viable.

A vascular access ASC would bring one more specialty to the Rocky Mount area. This would have the complimentary value of expanding the local medical care knowledge base. The ASC would be required by licensure and certification standards to make arrangements with local hospitals for emergency coverage. The presence of a vascular access ASC well operated, will prevent emergency after hours demand for this service. Moreover, the vascular access ASC will be organized to accommodate any after hour emergency patients with a first-thing, next-day schedule slot.

CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the SMFP and the need is sufficient to support the proposed special need adjustment to the 2023 SMFP.

EXHIBIT M

Acute Care Committee Agency Report
Adjusted Need Petition
for the Nash County Operating Room Service Area
in the 2023 State Medical Facilities Plan

Petitioner:
Carolina Vascular Care, PLLC
PO Box 1276
Morrisville, NC 27560

Contact:
Karn Gupta, MD
guptakarn@gmail.com
(252) 220-5470

Request:
Carolina Vascular Care requests a special need determination for one a single specialty ambulatory surgical center (ASC) with one operating room (OR) dedicated to vascular access (VA) in the Nash County service area in the *2023 State Medical Facilities Plan* (*SMFP*).

Background Information:
Chapter Two of the SMFP notes that during the summer, the Agency accepts petitions that "involve requests for adjustments to need determinations in the Proposed SMFP. Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies." It should be noted that any person might submit a certificate of need (CON) application for a need determination in the SMFP. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The methodology uses growth in surgical procedures at a facility and service area population to determine needs. The Petitioner is correct that the Nash County service area is not likely to have a standard OR need determination in the foreseeable future due to both a stable population and the lack of substantial growth in procedures performed in Nash County. The only ORs in the service area are at Nash General Hospital, which has 13 shared ORs and one dedicated C-Section OR. The hospital has a surplus of 5.21 ORs in the Proposed 2023 SMFP. Even though the Petitioner proposes to locate in Nash County, they intend to serve a larger area. The Petition specifically mentions Edgecombe, Halifax, Northampton and Wilson, in addition to Nash. Taken together, these four service areas have a surplus of 23.39 ORs. (Halifax and Northampton comprise a multicounty service area because Northampton has no licensed ORs.)

The SHCC first received a petition regarding VA centers in 2017 with a request to exclude VA ASCs from the methodology; the petition was denied. The same petitioners submitted a summer petition in 2017 for a demonstration project. The petition proposed two centers in each of the six health service areas (HSA) (see Appendix A of the SMFP for a listing of HSAs). The decline in reimbursement for VA procedures performed in physician-office-based laboratories (OBL) was a major basis for the petition. The petitioners argued that ASCs were the only viable option for continued non-hospital VA care. Based on the data available at that time, it did not appear that the number of patients could support 12 VA centers. Additionally, the SHCC opined that the appropriateness and efficacy of providing VA procedures in an outpatient setting was not in question, and thus did not need to be demonstrated. The SHCC received a third petition in 2018 requesting an adjusted need determination for one VA ASC in the Pitt/Greene/Hyde/Tyrrell service area. The petitioner again cited reductions in OBL reimbursement as a basis for the request. The Agency observed that reimbursements were in flux and it was unclear that rates were consistently being reduced in OBLs. The SHCC denied the petition and recommended that those interested in developing VA centers apply for ORs based on standard need determinations.

Certificates of need were subsequently issued to two VA ASCs in response to need determinations in the 2018 SMFP. Metrolina Vascular Access Care in Mecklenburg County was licensed on April 29, 2022. RAC Surgery Center in Wake County was licensed on March 19, 2021. Each ASC has one OR. Neither facility has been in operation long enough to provide a full year of data.

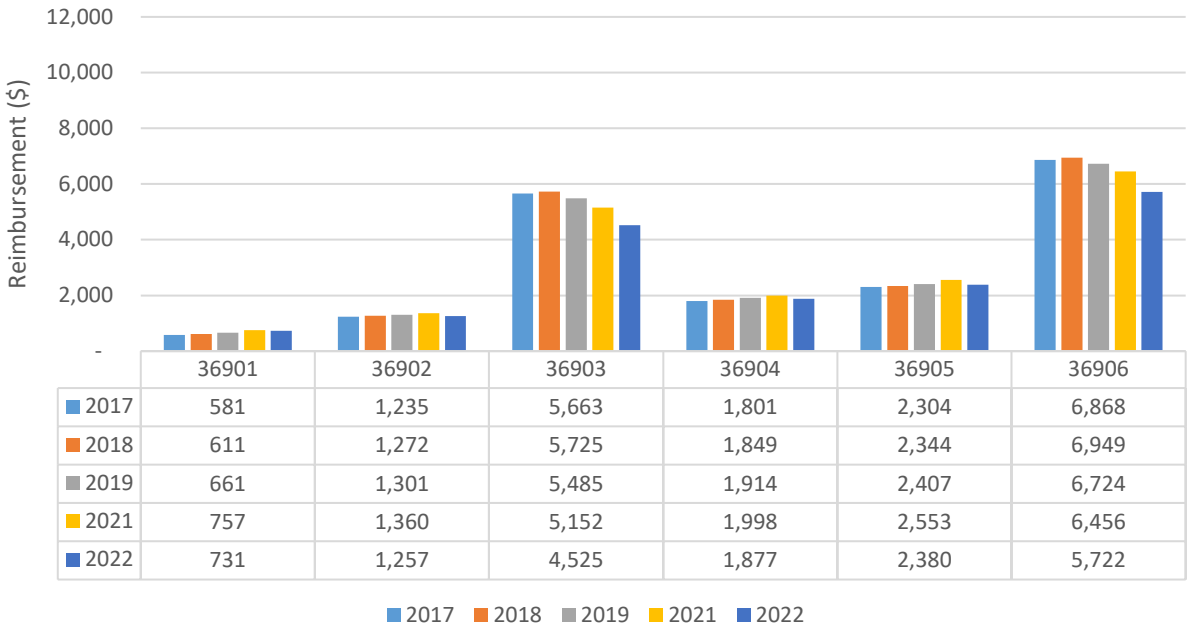
Analysis/Implications:
Like previous petitions, the current Petition cites reductions OBL reimbursements as a main motivation for the request. These changes began in 2017 when the Centers for Medicare and Medicaid Services (CMS) established requirements for procedures billed together more than 75% of the time to be bundled. As a result, commonly performed VA procedures experienced significant Medicare reimbursement cuts.[1] With these reductions have come increases in reimbursement for VA procedures at ASCs. These changes, however, were not consistent.

Figures 1 and 2 show changes in annual OBL reimbursement rates since 2017.[2] Rates for 2020 were not readily available. The first row of numbers below each chart shows the Healthcare Common Procedure Coding System (HCPCS) codes. The remaining rows are reported to be global national reimbursement rates for each procedure for each year. OBL reimbursement rates have remained relatively stable for most procedures. However, rates for the codes with the highest reimbursements, 36903 and 36906, have decreased by 20% and 17%, respectively. In contrast, rates for all ASC procedures except 36901 have fluctuated over this same time period. ASC reimbursement for 36903 and 36906 increased 39% and 16%, respectively.

[1] McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022).

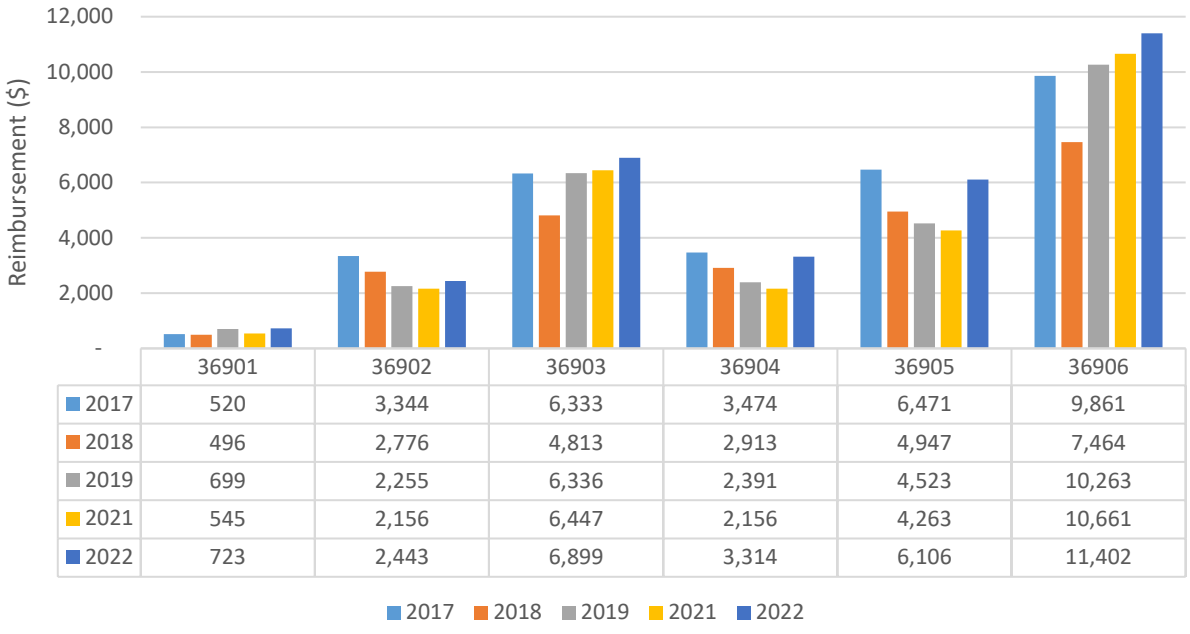
[2] *2017 and 2018 rates:* McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022). *2019 rates:* Litchfield, Terry (June 2019). Dialysis Access Coding Essentials, Recent Changes and Location Distinctions. *Endovascular Today* (18:6). Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions - Endovascular Today (evtoday.com) (accessed August 7, 2022). *2021 rates:* Greis, Jason S., Downing, Scott O., & Cilek, Jake A. (August 2021). CMS Proposes Steep Cuts to Office-Based Dialysis Vascular Access Reimbursement …Again! Bensch Healthcare+:Health Care & Life Sciences Client Bulletin. (accessed August 7, 2022). *2022 rates:* Petition.

Figure 1. OBL Reimbursement



	36901	36902	36903	36904	36905	36906
2017	581	1,235	5,663	1,801	2,304	6,868
2018	611	1,272	5,725	1,849	2,344	6,949
2019	661	1,301	5,485	1,914	2,407	6,724
2021	757	1,360	5,152	1,998	2,553	6,456
2022	731	1,257	4,525	1,877	2,380	5,722

Figure 2. ASC Reimbursement



	36901	36902	36903	36904	36905	36906
2017	520	3,344	6,333	3,474	6,471	9,861
2018	496	2,776	4,813	2,913	4,947	7,464
2019	699	2,255	6,336	2,391	4,523	10,263
2021	545	2,156	6,447	2,156	4,263	10,661
2022	723	2,443	6,899	3,314	6,106	11,402

HCPCS	Description
36901	Angiogram of Access (Fistulagram)
36902	Angiogram with Angioplasty
36903	Angiogram with Stent

HCPCS	Description
36904	Thrombectomy
36905	Thrombectomy with Angioplasty
36906	Thrombectomy with Stent

Litchfield (2019)[3] noted that

> The cut in the physician office payment was a combination of items, but the primary driver was the time for the procedure, which was significantly less than in the older codes. When the new codes came into the physician office fee schedule, it reflected that new value for the new codes. The valuation method for the ambulatory surgery center (ASC) and hospital outpatient department (HOPD) is different from that for the Physician Fee Schedule. For the HOPD, the procedures are assigned ambulatory payment classifications that are groupings of similar codes for endovascular procedures. The ASC payment is cross walked from the HOPD rate and discounted. This valuation methodology difference is why the new codes are paid very differently, and the rate increase is consistent with CMS methodology. Despite some concerns about growing utilization, this was not a signal from CMS to create ASCs nor was it a penalty for physician office surgery centers, but merely the way CMS prices new code.

Regardless of the rationale for the changes in reimbursement, the changes have, in fact, occurred. Many segments of medical care have experienced reductions in CMS reimbursement rates. It is unknown whether OBL VA procedures have received comparatively steeper reductions.

Anecdotal information claims that OBLs can no longer afford to operate. The American Society of Diagnostic and Interventional Nephrology (ASDIN) reported that nearly 20% of OBLs closed as a result of the 2017 rate reductions.[4] The Agency attempted to verify this data but could not do so. The 20% figure appears to be based on a survey of ASDIN members. It is unknown what proportion of OBLs in the country are represented in the ASDIN membership. It is also unknown what proportion of survey recipients responded to the survey. The Agency could not locate more recent data on subsequent closures.

The Agency acknowledges that access to VA services is needed throughout the state. Health Service Areas II through VI have about 3,400 dialysis patients residing in each HSA, while HSA I has about 2,000 patients.

The Agency also acknowledges that that OBLs may be at continued financial risk. However, the Agency does not recommend approval of a dedicated VA OR in Nash County in the absence of evidence of a need. Specifically, the SMFP does not have a need determination methodology for ASCs. Rather, need determinations in the SMFP are for ORs. CON applications specify the location of the proposed ORs (hospitals or ASC). The Petition does not indicate that Petitioner discussed access to VA services with any of the providers in the service areas they propose to serve, all of which have a surplus of ORs. We note that such a discussion does not necessarily imply that services would be provided in the manner that VA patients are currently normally seen in a hospital. Rather, a hospital may consider relocating an OR to an ASC in partnership with the Petitioner.

In considering alternatives to the Petitioner's request, the Agency investigated the potential utilization of dedicated VA ORs. In CY 2021, dialysis providers reported serving 19,302 patients. If we assume that each patient will need two VA procedures annually, NC patients will need a

[3] Litchfield, Terry. June 2019. Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions. *Endovascular Today*. 18:6.
[4] Litchfield, 2019.

total of 38,604 procedures. This number of procedures calculates to 19,302 surgical hours, based on RAC Surgery Center's reported average case time of 30 minutes. The SMFP methodology anticipates that the average OR will be staffed and utilized at least 75% of the available time, for a total of 1,312 hours annually. Using this standard, it is possible that the state could potentially support 15 VA ORs (19,302/1,312 = 14.71), if **all** procedures were performed in dedicated VA ORs. This situation is highly unlikely, though, because there will always be areas where a hospital or OBL is the best or perhaps only reasonably accessible option.

Agency Recommendation:
Given available information and comments submitted by the August 11, 2021 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to include a need determination for one VA ASC in Nash County in the *2023 SMFP*.

As an alternative to the submission of *ad hoc* petitions for VA ORs in specific service areas, the Agency recommends consideration of the following:

- Approval of one dedicated ambulatory VA OR in each of the six HSAs in the state, for a total of six VA ORs. VA ORs proposed pursuant to this need determination cannot be located in either Mecklenburg or Wake counties in light of the fact that there is a dedicated VA ASC with one OR in each of these counties. The VA OR can be located at an existing ASC, a proposed ASC, or on a hospital campus. If the OR is to be located at a hospital, it must be a dedicated ambulatory OR (i.e., in a hospital outpatient surgery department [HOPD]); and
- The VA ORs will be limited to serving dialysis patients; and
- CON-approved VA ORs and their procedures will be included in the standard OR planning inventory and methodology.