

PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

**Petition for Two Additional Operating Rooms in Onslow County in the
*2018 State Medical Facilities Plan***

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Wilmington Health, PLLC respectfully petitions the State Health Coordinating Council to create an adjusted need determination for two additional operating rooms in Onslow County in the *2018 State Medical Facilities Plan*, to be specifically designated for development in an ambulatory surgical facility that does not bill as a Hospital Outpatient Department (HOPD)¹. The petitioner further recommends that the need determination would include language to require applicants to demonstrate that they:

- 1) can reasonably project to increase the number of Onslow County residents receiving ambulatory surgery in their home county; and,
- 2) can achieve the performance standards in the CON rules without relying on surgical cases performed by surgeons who currently perform cases at licensed facilities in Onslow County.

BACKGROUND

Wilmington Health, the largest private, fully integrated, multispecialty medical group practice in Southeastern North Carolina, has been treating patients for nearly 45 years. Through more than 190 providers, including physicians and advanced care practitioners, Wilmington Health provides comprehensive medical care across multiple specialties and through many services including: imaging, audiology, cardiology, clinical pharmacy, clinical research, dermatology, diabetes education, ENT, endocrinology, gastroenterology, hearing aid services, hospitalist services, infectious diseases, infusion center, neurology, nutrition services, occupational health services, oncology/hematology, orthopedic surgery, physical therapy, plastic and reconstructive

¹ Although the CON statute defines the term “ambulatory surgical facility,” the Centers for Medicare and Medicaid Services uses the term “ASC” for reimbursement and distinguishes that from “Hospital Outpatient Departments.” For clarity, Wilmington Health uses the term “ASC” in this petition as well as the term “freestanding,” which further underscores the intent that such a facility not be a Hospital Outpatient Department.

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surgery, podiatry, pulmonology, allergy, radiology, rheumatology, sleep medicine, spinal intervention, general surgery, urology, vascular surgery, and weight management. Wilmington Health provides care to patients in over 20 locations in four counties, including Brunswick, New Hanover, Pender and Onslow.

Since 1990, Wilmington Health has operated a licensed, certified ambulatory surgical center (ASC) with three procedure rooms. In 2014, the practice received a certificate of need to convert its single-specialty ASC to a multi-specialty facility, which now allows the performance of procedures by physicians in the many surgical specialties that are represented at Wilmington Health. Earlier this month (July 2017), Wilmington Health, as part of a joint venture with EmergeOrtho and New Hanover Regional Medical Center (NHRMC) known as Cape Fear Surgical Center, received a certificate of need to relocate the existing multi-specialty procedure rooms to a new ASC in Wilmington, along with three existing operating rooms currently owned by NHRMC.

Wilmington Health has demonstrated a commitment to providing high quality, low cost healthcare to all of its patients, in particular through its ACO participation. In 2012, Wilmington Health created Physicians Healthcare Collaborative (PHC), an ACO, which was accepted as an ACO into the Medicare Shared Savings Program (MSSP) along with 105 other organizations across the country in January of 2013. In 2015, only two ACOs in the country had lower costs and higher quality than PHC. As of the most recent data reported by cms.data.gov, PHC has 98 percent quality scores, is the lowest cost ACO in North Carolina and ranks 12th in costs across all ACOs. PHC has reduced admissions by 33 percent over the last five years and admissions are currently 45 percent below the ACO average. Through the efforts of PHC, emergency room visits are 46 percent below the national average and have been reduced by 10 percent over the last five years.

Further, in July 2012, Wilmington Health partnered with Blue Cross and Blue Shield of North Carolina (BCBSNC) to form an ACO agreement, thereby expanding access to these benefits to patients of the largest commercial insurer in the state. This was the first insurer-provider ACO in the region. In August of 2013, NHRMC, Wilmington Health and BCBSNC launched an Accountable Care Alliance to enhance care and provide greater value for healthcare consumers in Southeastern North Carolina. The first of its kind in North Carolina, this unique collaboration brings together an insurer, a hospital system and the region's largest independent multi-specialty clinic to better meet the healthcare needs of patients. The Alliance focuses on quality of care, greater satisfaction and experience, improved access and affordability.

In 2013, Wilmington Health was named a 2013 Acclaim Award Honoree by the American Medical Group Association (AMGA). The prestigious honor is awarded annually to only three national healthcare organizations. Previous esteemed Acclaim Award Honorees include Mayo Clinic Health System, Johns Hopkins Medicine, and The Cleveland Clinic.

For patients cared for in one of Wilmington Health's 20 office locations, the data collected through the ACO allows the practice and its providers to track their performance, as noted above, while also understanding areas for improvement. While Wilmington Health has done very well in its physician clinics and ASC in New Hanover County, many of its patients originate

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in other counties, such as Onslow, but do not have access to care in a freestanding setting in that county. Having freestanding dedicated ambulatory operating rooms in Onslow County would extend the benefits of the Wilmington Health ACO to patients that currently must receive surgery services in another facility, typically in another county. The costs and charges would be lower than hospital-based care due to the freestanding ASC setting and because of Wilmington Health's ACO participation status.

Wilmington Health has had an office in Onslow County since 2010. The office is currently staffed with eight full-time providers, including gastroenterologists and cardiologists who live in Onslow County. In addition, several specialties provide care on a rotating basis, including pulmonology, urology, ENT and endocrinology, among others. The office also provides walk-in visits for family medicine and urgent care services 12 hours per day, seven days per week. Each year, physicians at Wilmington Health treat thousands of patients from Onslow County at offices in Onslow and New Hanover counties, many of whom require surgery. While some of Wilmington Health's surgeons have applied for privileges at Onslow Memorial Hospital, these efforts have been rejected. In addition, there is no non-hospital based option for patients wishing to have surgery in such a facility. Today, the only option for Onslow County patients choosing a Wilmington Health surgeon is to have their surgery performed in New Hanover County, where the surgeons have privileges at multiple facilities—hospital-based and non-hospital based. This places undue stress and burden on patients, who could be treated in their home county, particularly if a freestanding ASC were available.

Wilmington Health understands that the need methodology for operating rooms has been revised for the *Proposed 2018 SMFP*. We support the changes that have been made and appreciate the many hours of work that went into the new methodology. We also recognize, however, that any methodology, particularly one as complex as the operating room methodology, cannot address every potential issue. Specifically, we understand that the 2016-2017 OR Methodology Workgroup considered some comments from the public regarding the definition of service area as the county (or multi-county area) in which patients had their surgery *performed*, not the county in which patients *reside*. While this may be appropriate for showing the need for operating rooms driven by patient behavior, it does not account for patients leaving their home county for care because of a lack of access to facilities in their home county, particularly ASCs. We believe that this petition identifies a need that neither the old nor the new methodology addresses: that thousands of patients from Onslow County leave the county each year for ambulatory surgery that could be provided in their home county.

REASON FOR THE REQUESTED ADJUSTMENT

Wilmington Health already owns and operates a licensed, certified ambulatory surgical facility in New Hanover County, which is approved for the performance of multiple surgical specialties. In addition, surgeons at Wilmington Health have privileges to practice at the hospital and the other ASC in New Hanover County. As such, this petition is not driven by the practice's need to develop a facility to which its physicians can refer and in which its surgeons can perform cases. Rather, it is driven by the desire to prevent patients from Onslow County from leaving their county to access outpatient surgery, particularly in a freestanding (i.e. non-hospital based billing) setting.

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As a large, multi-specialty practice that serves patients from several counties, Wilmington Health is well aware of the number of patients who leave Onslow County for surgery in other counties. Its physicians treat thousands of patients per year that require surgery, some of whom are referred to other practices, and many of whom receive surgical care from its surgeons in many specialties. As such, Wilmington Health believes there is a need for a freestanding ASC in Onslow County, as presented in the following sections.

High Outmigration for Ambulatory Surgery

Each year, more Onslow County residents have outpatient surgery performed outside the county than in the county. As shown in the table below, this number is increasing.

Onslow County Ambulatory Surgical Cases

	<i>FY 2014</i>	<i>FY 2015</i>	<i>FY 2016</i>
Cases performed outside Onslow County	5,768	6,045	6,219
Total Cases	9,067	9,471	10,368
Outmigration Percentage	63.6%	63.8%	60.0%

Source: Healthcare Planning and Certificate of Need Section database

It should be noted that while it appears that the number of cases performed in the county is increasing and the outmigration is decreasing, Wilmington Health believes this is based on a temporary phenomenon. Specifically, surgical cases from the Naval Medical Center Camp Lejeune were temporarily referred to Onslow Memorial Hospital while renovations were underway at the base hospital; this factor accounts for at least some of the growth in cases reported at Onslow Memorial Hospital. Nonetheless, the number of cases performed outside the county has steadily increased, indicating a lack of access within the county. While the reason that patients have surgery in other counties likely varies, approximately one-quarter of them were performed in the freestanding ASCs closest to Onslow County, which are in New Hanover, Carteret and Pitt counties, and one-half of these cases (50.3%) were performed in New Hanover County, in both freestanding and hospital-based settings.

Further, this level of outmigration is much higher than the average for similarly sized counties. As shown in the table below, the average outmigration is 26.9 percent in the top 12 counties, including Onslow County.

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<i>County</i>	<i>2015 Population</i>	<i>Non-Hospital Based ORs</i>	<i>Percent of Ambulatory Surgery Performed Outside the County (Outmigration)</i>
Mecklenburg	1,035,605	26	6.8%
Wake	1,007,631	27	18.1%
Guilford	517,124	30	19.6%
Forsyth	366,543	7*	13.8%
Cumberland	328,860	11	22.5%
Durham	297,219	8	20.7%
Buncombe	254,836	4	11.9%
New Hanover	220,231	13*	5.6%
Union	219,992	3*	67.4%
Gaston	212,636	6	40.8%
Cabarrus	195,714	6	31.9%
Onslow	194,636	0	63.8%
Average	404,252	12	26.9%

*Includes operating rooms that have received a CON or have been proposed in a CON application; chronically underutilized facilities are excluded.

Sources: Population data from NC OSBM; OR data from *Proposed 2018 SMFP* and CON reports; Outmigration from Healthcare Planning and CON Section database.

As shown, Onslow County stands out among the other counties in its lack of operating rooms in a freestanding setting and the percentage of its population that leaves the county for outpatient surgery. While some counties on the list, including Cabarrus, Gaston and Union have more than 30 percent of patients leaving the county for ambulatory surgery, these counties are contiguous to a large metropolitan area (Mecklenburg County) with numerous facilities. In contrast, Onslow County is contiguous to only one county with a freestanding ASC, Carteret County, and that facility is nearly one hour away from Jacksonville. Patients traveling to New Hanover County, where the majority of outmigrating patients receive care, must travel over an hour to the closest surgical facility. The distance to facilities in other counties places an extra burden on patients who must travel for care.

Ability to Support an Ambulatory Surgical Facility

Wilmington Health recognizes that the size of a county's population is not the only determinant of its ability to sustain an ASC. Using the counties in the table above and outpatient surgery cases from the Healthcare Planning database, the following table shows the number of outpatient cases per freestanding ambulatory surgical operating room in each county. This is not the number of cases performed in each freestanding operating room; rather, it indicates the ratio of all outpatient cases to freestanding operating rooms. Certainly some outpatient cases need to be performed in a hospital-based setting; this analysis shows the range of outpatient cases performed in these counties per freestanding operating room, which provides a proxy for

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the range of freestanding operating rooms that can be supported for the number of outpatient cases.

<i>County</i>	<i>Non-Hospital Based ORs</i>	<i>Ambulatory Surgery Cases (all sites) (FY 2016)</i>	<i>OP Cases per Non-Hospital Based OR</i>
Mecklenburg	26	54,059	2,079
Wake	27	48,220	1,722
Guilford	30	32,337	1,078
Forsyth	7*	25,754	3,679
Cumberland	11	17,987	1,635
Durham	8	12,952	1,619
Buncombe	4	17,313	4,328
New Hanover	13*	15,490	1,192
Union	3*	13,778	4,593
Gaston	6	15,940	2,657
Cabarrus	6	13,031	2,172
Onslow	0	10,368	0
Average (excluding Onslow County)			2,432

Although the percentage of these cases performed in a hospital versus freestanding setting varies among the counties, the data show that a ratio of between 1,078 and 4,593 ambulatory surgery cases per freestanding operating room exists in these counties. Using the more conservative, higher end of the range (4,593), with 10,368 ambulatory surgery cases, Onslow County can support a minimum of 2.3 operating rooms in a freestanding setting. Thus, the petition’s proposed two operating rooms to be developed in a freestanding ASC can reasonably be supported.

Lack of Patient Origin/Outmigration Data in the Methodology

As noted above, an analysis of outmigration for ambulatory surgery is not part of the proposed or former need methodology for operating rooms, and the amount of outmigration certainly varies across the state. Indeed, some counties have no operating rooms of any type, while others are likely too small to support a freestanding ASC. Wilmington Health believes that Onslow County is unique in its ability to support a freestanding ASC, which will provide high quality, lower cost care that is more accessible to county residents, but without negatively impacting the hospital. In fact, Wilmington Health believes that the development of an ASC in the county will attract more surgeons to the community, who will perform some of their cases, both inpatient and outpatient, in the hospital-based operating rooms.

While the use of a site-of-care driven service area is reasonable and perhaps the most effective way to determine the need for additional operating rooms in a statewide methodology, it does not address the particular situation in Onslow County. In essence, the need for ambulatory

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operating rooms to serve a majority of the Onslow County patient population is driving the need for operating rooms in other counties, New Hanover in particular, as discussed below. Without the approval of a special need petition that addresses this issue, or without existing providers with the ability and willingness to utilize existing resources to create a freestanding ASC, the methodology will never address the need of these patients for this level of care in their home county.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

Without the approval of the petition, thousands of patients each year will continue leaving the county for surgery that could be provided closer to home in a lower cost setting. Moreover, the new methodology, while robust and effective in most situations, would continue to determine need for operating rooms to serve the Onslow County population based on where they go to receive their care, even if they would prefer to remain in their home county. Future need for operating rooms will be created in areas where these patients must go for care, without regard to the potential of serving them closer to home.

ALTERNATIVES CONSIDERED

Wilmington Health considered three primary alternatives, including working with the hospital to develop an ASC, petitioning for one additional operating room, and petitioning for two additional operating rooms. Each of these is discussed below.

Develop an ASC with the Hospital's Existing Operating Rooms

Wilmington Health strives to partner with the local hospitals in counties where it has offices, including Onslow Memorial Hospital. As discussed above, the goal of this petition is to allow patients that currently leave the county for ambulatory surgery to have access to a freestanding ASC within their home county. Wilmington Health recognizes the need for Onslow Memorial Hospital to maintain its inventory of hospital-based operating rooms; the revenue from the surgical cases performed in those rooms helps to sustain the hospital, which is a safety net provider to the community. Onslow Memorial Hospital, like many others, faces ongoing challenges as healthcare evolves, including a phase-out of special payments for Tricare patients, which comprise a significant percentage of the hospital's patients. Wilmington Health recognizes that numerous factors contribute to the hospital's thin operating margins and has no desire to contribute to an additional erosion of revenue. The need to ensure the ongoing viability of Onslow Memorial Hospital is the basis for the request that the need determination, if approved, be limited to those who can demonstrate improved access to patients currently leaving the county for care. In addition, Wilmington Health is working with the hospital to develop and manage its Accountable Care Organization (ACO), which will help to ensure financial stability as the demand for value-based care increases.

Another consideration driving the need to request additional operating rooms is the high cost of physician partnership in existing operating rooms. Even if the hospital were able to use some of its existing operating rooms to develop an ASC, physicians would be required to pay fair market value, which is based on the revenue associated with those operating rooms, not just the capital

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cost associated with building an ASC. As the SHCC is aware, operating room revenue is substantial for most hospitals; thus, the valuation of existing operating rooms in such a transaction often results in a cost that is out of reach to many potential partners, and has, in the experience of Wilmington Health’s consultants, been a key factor in the demise of similar projects in the past.

Finally, while the *Proposed 2018 SMFP* shows a surplus of 3.3 operating rooms in Onslow County, Wilmington Health does not believe this accurately reflects the total utilization of the operating rooms at Onslow Memorial Hospital. The existing nine operating rooms at the hospital are located in two settings: five are within the main hospital and four are in a separate building near the main campus. All are hospital-based from a billing and reimbursement perspective. In addition to the surgical cases performed in the operating rooms that are included in the methodology, the hospital also reports on its license renewal application non-surgical cases that are performed as well. The table below includes these cases and shows the estimated surgical hours and operating room surplus by facility, using the methodology in the *Proposed 2018 SMFP*, but including non-surgical cases from the hospital’s license renewal application:

	<i>Onslow Memorial Hospital</i>	<i>Surgicare</i>
Ambulatory Cases (73.7 minutes each)	2,915	2,461
Inpatient Cases (124 minutes each)	1,141	0
Total Hours	5,939	3,023
Projected with Growth Factor (4.46)	6,204	3,158
Operating Rooms Needed (1,500 cases each)	4.1	2.1
Existing Operating Rooms	5.0	4.0
Deficit/Surplus	0.9	1.9

Source: 2017 Hospital License Renewal Application; cystoscopy cases are assumed to be performed in the cystoscopy procedure room and are therefore excluded.

As shown, the hospital does not have a whole operating room to contribute, particularly if additional growth in the future is considered. Moreover, the operating rooms within the hospital are relatively new, as they were constructed as part of the hospital’s Emergency Department and Operating Room Expansion in the mid-2000s. Thus, they have plenty of useful life left and closing one or more to be relocated to an ASC is not a viable option. Wilmington Health understands that they are also encumbered with HUD-insured bonds that paid for the expansion project, and are unlikely to be able to be removed from the hospital for such a project. Surgicare also has fewer than two rooms to contribute, and relocating more than one operating room might create capacity constraints in the near future and not allow for additional growth at the facility. A one-room ASC is also not ideal.

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While Wilmington Health has approached Onslow Memorial Hospital regarding its willingness to develop a freestanding ASC with its existing operating rooms, the hospital has declined, and given the reasons discussed above, Wilmington Health understands the hospital's decision. Wilmington Health is willing to partner with the hospital to develop a freestanding ASC as it has done elsewhere; however, under current CON rules, an application with the hospital as an applicant would not be approved because of its available capacity, even though that capacity is all hospital-based and unable to be used by Wilmington Health's (and other practices') surgeons. Nonetheless, if the petition is approved Wilmington Health does intend to work with Onslow Memorial Hospital, if it is willing and if it is possible under the regulations, to develop the facility.

Petition for One Operating Room

Wilmington Health also considered petitioning for just one additional operating room. While this would provide some remedy to the high outmigration from Onslow County, it would likely prevent a new provider from proposing to develop the operating rooms. For example, a one-room ASC may be feasible in some rare instances, but most of the one-OR ASCs in the state are underutilized. Even the current single-specialty ASC demonstration projects include two operating rooms. While the allocation of one additional operating room would be a superior alternative compared to the status quo in which no additional operating rooms are allocated, Wilmington Health believes that a need determination for two additional operating rooms is the best alternative.

Petition for Two Operating Rooms in a Freestanding ASC Setting

As demonstrated by multiple analyses in this petition, there is a clear need for access to a freestanding ASC by Onslow County residents. A two-operating room facility, particularly with the recommended stipulations would meet the need without unnecessarily duplicating existing resources.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

Wilmington Health does not believe that approval of the petition would unnecessarily duplicate existing resources. First, there are no freestanding ambulatory operating rooms in the county; thus, the development of a freestanding ASC would not duplicate any resources within the county. Second, the methodology in the *Proposed 2018 SMFP* generates need within a county when a facility shows a deficit of operating rooms, even if other facilities show a surplus. The challenge is that Onslow County has only one facility and thousands of patients that leave the county each year for outpatient surgery. As a result, the need for surgical capacity is shown in other counties where these patients go for care. If the petition is approved, Wilmington Health believes the outmigration will diminish, and the need for additional operating rooms in other counties will similarly decline. For example, New Hanover County, where most of Onslow County residents that leave the county go for surgery, has had a need determination for a total of four (4) operating rooms in the last two *SMFPs*, and is likely to have a need in future years as well. If the petition is approved, and Onslow County residents are provided the opportunity for care in an ASC in their home county, the need in New Hanover County will decrease. For

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example, if only one-half of the 3,129 Onslow County patients who had outpatient surgery in New Hanover County in FY 2016 received care in their home county in the future, the total number of operating rooms needed in New Hanover County would decrease by one to two rooms, depending on facility.

As an example, under the new operating room methodology in the *Proposed 2018 SMFP*, if Wilmington Health operated a licensed ASC in Onslow County with one operating room which performed 3,110 surgical cases in FY 2016 (or one-half of the surgical cases performed on Onslow County residents in other counties in FY 2016), and assuming it was in Group 6 with the average case time for that group (70.3 minutes), Table 6B for Onslow County would look as follows (with non-applicable columns removed for brevity):

<i>Service Area</i>	<i>Facility</i>	<i>Total Adjusted Estimated Surgical Hours</i>	<i>Projected Surgical Hours for 2020</i>	<i>Projected Surgical ORs Required in 2020</i>	<i>Adjusted Planning Inventory</i>	<i>Projected OR Deficit/Surplus</i>	<i>Service Area Need</i>
Onslow	Onslow Memorial Hospital	8,186	8,551	5.70	9	-3.30	
	Hypothetical ASC	3,644	3,807	2.90	1	1.9	
Onslow Total							2.0

Although this is just a hypothetical and a one-OR facility would not likely be able to perform such volume, the reality is that these patients are already driving the need for operating rooms—but in another county. And if they were able to have their surgery performed in their home county, the need for operating rooms to perform those surgeries would be generated by the methodology in the *Proposed 2018 SMFP*, despite the apparent capacity at the hospital. Given this fact, approval of the petition would not unnecessarily duplicate existing capacity, but would instead allow the capacity to be relocated to where it can provide better access to the patients who need it.

In addition, Wilmington Health believes that the requirements of the need determination help prevent unnecessary duplication. In particular, requiring applicants to demonstrate that they can decrease the outmigration of ambulatory surgery patients and do not propose to meet the utilization requirements by merely shifting volume from existing operating rooms in the county will help ensure that a facility approved pursuant to the need determination will achieve the benefits of the petition without unnecessarily duplicating existing resources.

EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES

Wilmington Health believes the petition is consistent with the three basic principles: quality and safety, access and value. First, quality and safety are clearly enhanced through the development of the operating rooms in a freestanding ASC.

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Access is also promoted through the development of a new freestanding ASC in the county. The availability of such a facility for patients to receive their surgery, particularly in their home county, will enhance competition and access to care.

The petition also promotes value. As the SHCC is well aware, costs and charges are lower in a freestanding ASC setting. While the need for hospital-based care also exists, Wilmington Health believes that a two-operating room ASC can be developed without necessitating a decline in utilization at the local safety net hospital provider.

CONCLUSION

Wilmington Health believes that the special circumstances in Onslow County warrant the need for two additional operating rooms to be developed in a freestanding ambulatory surgical facility. Specifically:

- Onslow County has one of the highest outmigration rates for ambulatory surgery among counties of a similarly sized population;
- Onslow County has both the population and the number of ambulatory surgery cases to support a freestanding ASC;
- Neither the former nor the current operating room methodology define the service areas and determine need based on where patients live, but by where they receive care, even if they have few or no local options for receiving care from their preferred physician; and,
- The specific conditions proposed for the need determination would help ensure development of an ASC without unnecessary duplication.

These factors contribute to unique circumstances in Onslow County that support a special need determination for two additional operating rooms to be developed in a freestanding ASC setting.