

**Comments in Opposition to Novant Health New Hanover Regional Medical Center’s Petition
for an Adjusted Need Determination to Remove the Need Determination for One Unit of Cardiac
Catheterization Equipment in New Hanover County
in the 2023 State Medical Facilities Plan**

COMMENTER

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INTRODUCTION

Novant Health New Hanover Regional Medical Center (“NH New Hanover”) filed a petition for an adjusted need determination in the 2023 SMFP to remove the need for additional cardiac catheterization equipment in New Hanover County. Wilmington Health opposes the petition and requests that it be denied. Please note that while Wilmington Health refers in these comments to the need expressed in NH New Hanover’s petition relating to Brunswick County, Wilmington Health is not taking a position for or against the petition for an adjusted need determination in Brunswick County, except to the extent that the SHCC would approve a need in Brunswick County in place of the need in New Hanover County.

WILMINGTON HEALTH’S RATIONALE FOR OPPOSITION

Wilmington Health believes that there are numerous reasons to deny the NH New Hanover petition. Most importantly, there is no evidence that the existing methodology fails to appropriately evaluate cardiac catheterization utilization and need in New Hanover County, which shows a need for additional cardiac catheterization equipment. Such approval would be contrary to the standard need methodology and contrary to the process and procedures outlined in the SMFP for making changes to the SMFP and the purpose of CON Law, which recognizes that the development of necessary healthcare services in defined service areas provides “assurance of economical and readily available health care.” NCGS § 131E-175(2). Removal of the need determination in New Hanover County threatens the health and welfare of New Hanover County residents as well as those from other counties seeking care in the county and should be avoided. The following discussion provides both qualitative and quantitative reasons that the petition should be denied.

1. Deficit of Cardiac Catheterization Equipment

The Proposed 2023 SMFP cardiac catheterization methodology shows that New Hanover County has a deficit of cardiac catheterization equipment. The calculated deficit of one unit of cardiac catheterization equipment for New Hanover County was calculated by applying the standard methodology found on page 302 of the Proposed 2023 SMFP. The need for one unit of cardiac catheterization in New Hanover County was accurately calculated utilizing the methodology found

in Chapter 17A of the *SMFP* and should remain as written. Approval of the NH New Hanover petition to remove a need determination in New Hanover County for cardiac catheterization equipment would clearly result in the denial of access to cardiac cath resources in the service area.

As demonstrated by the appropriate and accurate application of the need determination methodology, New Hanover County has sufficient procedure volume to support the development of an additional unit of cardiac catheterization equipment in the New Hanover County service area. While the methodology is not based on projected utilization, cardiac cath volume in New Hanover County has grown steadily for many years, and the need can only be expected to increase with population growth and aging. Of note, the methodology is based on patients from any location that receive cardiac catheterization services in New Hanover County. This approach is similar to many other methodologies, including acute care beds, operating rooms, MRI scanners, PET scanners, and linear accelerators. In recent years, New Hanover County has generated need determinations for each of the listed services; however, NH New Hanover has never requested that the SHCC “reallocate” the need determination because patients were traveling from other counties into New Hanover for services, as it is with this petition. Because NH New Hanover is petitioning based on a fundamental premise of the methodology, which is shared with numerous other methodologies, Wilmington Health believes its petition cannot be approved without calling into question the same approach in the other methodologies.

The petitioner chooses to focus on the number of Brunswick County patients utilizing cardiac catheterization equipment at NH New Hanover. However, the petitioner fails to acknowledge that this is central to the present methodology, as it is with the other services listed above. The petitioner provides historical data showing the Brunswick County utilization of cardiac cath procedures at NH New Hanover during the time period 2016 through 2021 and calculates annualized data for 2022. The petitioner states that the number of Brunswick County patients receiving cardiac catheterization procedures at NH New Hanover has increased annually since 2016, with a 1.2 percent decrease in 2020. Yet the petitioner fails to acknowledge that the 2022 annualized data represents a -3.2 percent growth rate for Brunswick County residents utilizing cardiac cath services in the New Hanover service area. While growth and utilization of cardiac cath equipment by Brunswick County residents in New Hanover County has risen in the past, the most recent data shows that growth has remarkably slowed from 27.6 percent in 2017 to 3.7 percent in 2021 and -3.2 percent in 2022 (calculated using annualized data). This is in stark contrast to the growth in total procedures performed in New Hanover County, which grew an incredible 26 percent in one year from FY 2020 to FY 2021 (5,708 procedures in the *2022 SMFP* to 7,220 in the *Proposed 2023 SMFP*).

Furthermore, it should be noted that Brunswick County is currently served one day a week by a mobile cardiac cath unit located at NH Brunswick Medical Center (NH Brunswick). The mobile unit has the capacity to perform 300 procedures on that one day yet has been underutilized since it was put into service. A review of data from past *SMFPs* show that in 2019 only eight procedures were performed, in 2020 the utilization rose to 32 procedures and in 2021 utilization was only 35 procedures. These numbers demonstrate that there is more than sufficient capacity to serve residents of Brunswick County needing cardiac cath services. The request to add a cardiac cath need determination in Brunswick County in place of the need in New Hanover County should be denied on the basis that the service area is underutilizing healthcare resources currently in place and would be a costly misappropriation of healthcare resources when there is clearly a need in

the neighboring service area of New Hanover County. While NH New Hanover states that a mobile cardiac cath lab is not desirable for patient care, particularly for interventional procedures, what it fails to discuss is the option of electing full-time vendor-provided service, which would also allow the cath lab to be located inside the hospital. As the SHCC is aware through previous petitions, other hospitals in non-metro counties have found this approach sufficient to build up their program, including Caldwell Memorial Hospital and Pardee Memorial Hospital, both of which maintained “full-time” vendor-owned equipment inside the hospital until successfully petitioning for their own cath lab. While Wilmington Health is aware that the state’s mobile cardiac cath vendor owns nine such units, which do not appear to be fully utilized, certainly with the availability of two of those units that have been replaced at Caldwell and Pardee, the petitioner could proceed to contract for one of those units to be located in Brunswick County on a full-time basis, even inside the hospital, until the volume was sufficient to demonstrate the need for a fixed cath lab in Brunswick County.

NH New Hanover also appears to assume that the development of a fixed cath lab in Brunswick County would obviate the need for additional capacity in New Hanover County. While some patients may choose care in their home county, the petitioner cannot guarantee that all or even a specific portion of the patients currently coming to New Hanover County will instead choose NH Brunswick. The petitioner appears to assume that if the petitions are approved, NH Brunswick will be approved, and thereby able to direct patients accordingly. As the SHCC is aware, there is one other hospital and an existing ASC in Brunswick County as well, either of which could apply for the cath equipment, if allocated. Additional data militates against NH New Hanover’s assumption, particularly a review of patient origin reports from the other services with a similar, site-of-care based methodology, which demonstrate that even with services available in Brunswick County, patients continue to choose to travel into New Hanover County for care, as they likely will even if the SHCC approves the petitions. For example, based on patient origin data collected and aggregated by the Agency, in 2021, the majority of Brunswick County patients traveled outside of the county for services available in their home county, as shown below:

<i>Service</i>	<i>Percentage of Brunswick County Patients Served in Brunswick County</i>
GI Endoscopy	38.92%
Inpatient Surgery	27.77%
Acute Care	36.97%

Source: 2022 patient origin reports (FFY 2021 data), Accessed at: <https://info.ncdhhs.gov/dhsr/mfp/patientoriginreports.html>

While some services, like MRI, did show a higher percentage of patients remaining in the county for care, it is more likely that patients would leave their home county for an acute or invasive service, as shown above, than for a scheduled, standard outpatient imaging procedure. Thus, it is not certain that development of a fixed cardiac cath unit in Brunswick County, even if allowed, would dramatically decrease the number of Brunswick County residents that seek that service in New Hanover County.

Additionally, the petition refers to the trend for patients in the ZIP codes closer to South Carolina to travel into that state for care, rather than to Wilmington, given the distance. While this may be true, it is unlikely to change even if NH Brunswick’s petition is approved. Specifically, patients in

that portion of the county are much closer to McLeod Health Seacoast, in Little River, which is approved to provide diagnostic and interventional (PCI) cardiac catheterizations. According to Google Maps, Carolina Shores is less than eight miles from McLeod Health Seacoast in Little River but is more than 22 miles from NH Brunswick. Thus, even with a cardiac cath lab at NH Brunswick, it is likely that patients closer to South Carolina will continue to seek care outside the county. Similarly, patients in the Leland area of Brunswick County, from which are of Brunswick County NH New Hanover indicates that it receives its greatest number of patients, are approximately 22 miles from NH Brunswick, but less than 10 miles from NH New Hanover. By the petitioner’s own data, the largest portion of patients coming from Brunswick County to New Hanover County are more than twice as close to NH New Hanover than they are to NH Brunswick County. Therefore, the idea presented in the petition that an overwhelming number of patients would receive care in Brunswick County and elect not to receive care in New Hanover County is unsupported.

While the petition does not provide a methodology by which it assumes the projected number of patients that would receive services in Brunswick County instead of New Hanover County, it asserts that sufficient capacity would exist in New Hanover County as to obviate the need for the additional unit allocated in the *Proposed 2023 SMFP*. Wilmington Health believes this analysis is flawed for multiple reasons. First, even if the need determination in the *Proposed 2023 SMFP* were removed, by the petitioner’s own projections, utilization would exceed the 80 percent threshold in 2022 (for the *2024 SMFP*) and 2023 (for the *2025 SMFP*) before sufficient volume “shifted” to Brunswick County. Second, the petition provides no rationale for the cases it projects will be performed in Brunswick County instead of in New Hanover County; as such, the SHCC should not assume that the projections are reasonable. Third, data for counties similar to Brunswick in population (or even larger), scope of hospital services (no regional providers of tertiary, open-heart and similar services), and proximity to contiguous counties with regional, tertiary hospitals indicate that the number of cardiac catheterization procedures projected to be performed in Brunswick is unreasonable, as shown below.

County	2021 Population*	2021 Weighted Cath Procedures^
Brunswick	140,411	35
Harnett	134,847	333
Rowan	147,817	849
Alamance	173,384	986

*NC OSBM

^*Proposed 2023 SMFP*, Table 17A-3

While there are some counties with a similar population in which a higher number of procedures are performed, the facilities in these counties have operated interventional cardiac catheterization programs for many years and did not achieve these volumes within the first few years of developing their programs. Given this analysis, Wilmington Health believes that the most prudent approach is to maintain the need determination in New Hanover County, regardless of the SHCC’s decision on the Brunswick County petition, to ensure sufficient patient access to cardiac catheterization services.

2. Service Area and Need Methodology

Chapter 17A of the SMFP clearly identifies two distinct need determination methodologies for fixed cardiac catheterization equipment. First and foremost, both methodologies in the *SMFP* state that the service areas for cardiac catheterization equipment are the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1. By this definition, New Hanover County is one distinct service area and Brunswick County is a separate service area and must be considered as such when applying the need methodology. Methodology 1 for fixed cardiac catheterization equipment looks at the number of fixed cardiac cath equipment required in the service area for the number of procedures performed. The process does not consider in migration or outmigration of patients. The *SMFP* specifically states that this methodology is for service areas with at least one unit of equipment in the current inventory, which the New Hanover County service area meets. Methodology 2 is for cardiac catheterization equipment in a service area that does not have an existing unit of fixed cardiac catheterization equipment, like Brunswick County. Need is determined to exist when the number of cardiac catheterization procedures performed at any mobile site in the service area exceeds 240 procedures per year for each eight hours per week that the mobile equipment is operated at that site during the current reporting year.

As discussed previously, the mobile cath unit at NH Brunswick is underutilized, while the existing and approved cath units in New Hanover County are highly utilized and demonstrate need for another unit of equipment. The petitioner asserts that removing the need determination from New Hanover County is necessary to balance the “need” for cardiac catheterization equipment to be allocated in Brunswick County. However, this request is inappropriate for the summer petition cycle, in that it involves multiple service areas, which are in fact separate and distinct in the methodology. New Hanover County and Brunswick County are two distinct service areas for cardiac catheterization, and each has a separate need methodology to follow, Methodology 1 and Methodology 2, respectively. According to the process for adjustments found in Chapter 2 of the *SMFP*, changes to the service area definition and need methodology can have far reaching effects, and therefore, in order to receive adequate consideration for their impact must be pursued by filing a spring petition. While NH New Hanover has filed two separate petitions in an attempt to avoid this issue, the result of approving the two petitions would be the same: to allow the “swapping” of need determinations with an impact on multiple service areas with different applicable methodologies, which should be reviewed in the spring cycle. If the SHCC believes there is merit in finding a need for Brunswick County, it should not substitute the need in that service area with the need that exists in New Hanover County.

3. Precedent from Similar SHCC Petitions

In previous instances in which the SHCC approved a special need petition for a county without fixed cardiac catheterization equipment, the utilization of the mobile service in the county was significantly higher than it is in Brunswick County. In 2010, a petition from Central Carolina Hospital in Lee County demonstrated that its mobile unit was performing nearly 300 annual procedures in the one day per week that the mobile was on site¹. The SHCC determined that a need existed in Lee County but importantly did not adjust the need in any other service area. Of note, in multiple other petitions², counties without fixed cardiac cath equipment successfully

¹ https://info.ncdhhs.gov/dhsr/mfp/pets/2010/tec/0804_central.pdf

² Including petitions in 2002 for Randolph County and petitions in 2007 for Scotland and Halifax counties

requested need determinations, but in no instance was the utilization, inventory or need determination in the counties that had historically served those patients adjusted.

In the 2014 SMFP, the SHCC approved a petition from New Hanover Regional Medical Center which similarly requested that the need determination be removed, in that case due to special circumstances that led to a temporary increase in utilization. In its report³, however, the Agency referred to circumstances that do not exist today, stating, *“New Hanover Regional Medical Center has unique attributes...as well as being the only potential provider of cardiac catheterization services.”* As the Agency is aware, and as discussed below, such is not the case today.

In 2021, the Duke University Health System (DUHS) filed a summer petition that made a similar request. In the petition, DUHS requested an adjusted need determination for 46 acute care beds in the Wake County service area, and a corresponding removal of 68 acute care beds in the neighboring service area of Durham/Caswell, based on the concept that beds in Durham County were serving residents of Wake County, and that the approval of additional beds in Wake County would remove the need for capacity in Durham County. The petition also argued that recent need determinations in Durham County would provide sufficient capacity for the foreseeable future, particularly with a need determination in Wake County. In its analysis, the Agency found that, *“Historically, the Agency has recommended removal of an acute care bed need determination when the actual conditions in a service area are not adequately reflected in a component of the methodology, thereby causing a need determination. The Petitioner does not present evidence that this has occurred in the Durham/Caswell service area for the 2022 SMFP cycle.”* Wilmington Health believes that the NH New Hanover petition also fails to present evidence that the “actual conditions in a service area are not adequately reflected in a component of the methodology.” The DUHS petition was denied based on the Agency recommendation that the need determination for Durham/Caswell was appropriate and based on the need methodology in place and noted that *“...while the utilization by Duke University Health System hospitals created the need in the service area, another entity in the service area is eligible to apply for the beds.”*⁴ Novant Health’s petitions to remove cardiac cath need in New Hanover County and add need in Brunswick County mirrors the request of DUHS and both should be denied based on precedent set forth last year when DUHS’s requests were denied, particularly given the discussion in 4 below.

4. Opportunity to Increase Competition and Lower Costs in New Hanover County

NH New Hanover has been the sole provider of cardiac catheterization services in the New Hanover County service area for more than twenty years and has had an inventory of five units of cardiac catheterization equipment for over 10 years. For the first time in many years, the 2021 SMFP identified a need determination for one unit of cardiac catheterization equipment in the New Hanover County service area. Both NH New Hanover and Wilmington Health submitted applications, and the Agency found both applicants conforming with the applicable statutory and regulatory review criteria. Wilmington Health believes it is reasonable to assume that NH New Hanover is requesting the removal of the need determination from New Hanover County to prevent another entity from seeking approval to develop a competitive program in the service area. Considering that the CON law is intended to regulate healthcare for the purpose of controlling costs, utilization and distribution of new health service facilities, Wilmington Health

³ https://info.ncdhhs.gov/dhsr/mfp/pdf/2013/tec/0910_cc_newhanover_agencyrep.pdf

⁴ https://info.ncdhhs.gov/dhsr/mfp/pdf/2021/acsc/05_DukeWakeDurhamAgencyReport_v2_final.pdf

believes that efforts by NH New Hanover to limit competition, particularly from a high quality, lower cost provider, should be thwarted by supporting the standard methodology and the need determination it has generated.

Wilmington Health also believes that it is significant that the petition fails to truly address the Basic Principles, as the approval of the petition would be inconsistent with these Principles. Specifically, with respect to the Access Basic Principle, the *SMFP* states,

“Access barriers of time and distance are especially critical to rural areas and small communities. However, urban populations can experience similar access barriers. The SHCC recognizes that some essential, but unprofitable, medical services may require support by revenues gained from profitable services or other sources. The SHCC also recognizes a trend to the delivery of some services in more accessible, less complex, and less costly settings. Whenever verifiable data for outcome, satisfaction, safety, and costs for the delivery of such services to representative patient populations justify, the SHCC will balance the advantages of such ambulatory facilities with the needs for financial support of medically necessary but unprofitable care.” (emphasis added)

The Value Basic Principle also supports denial of the petition:

“Long-term enhancement of health care value will result from a State Medical Facilities Plan that promotes a balance of competition and collaboration and encourages innovation in health care delivery. The SHCC encourages the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care. The SHCC also recognizes the importance of balanced competition and market advantage in order to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery.” (emphasis added)

As noted in the petition, NH New Hanover is approved for units of six cardiac catheterization equipment. It does provide care to the medically underserved, but it is part of one of the largest health systems in the state, whose fiscal health is not in question. According to Table 17A-3, NH New Hanover is one of the highest volume cardiac catheterization providers in the state, second by only 10 procedures to UNC REX Hospital, which is located in a county with three other providers. As noted above the Certificate of Need Section has already determined that Wilmington Health could develop a cardiac catheterization program in conformity with the statutory and regulatory criteria. As also stated above, in the DUHS petition filed on the 2021 *SMFP*, the Agency noted that DUHS was not the only provider who might be interested in developing the additional beds needed in the service area. Similarly, Wilmington Health believes that the SHCC should recognize that maintaining the need generated by the standard methodology will provide the opportunity for a new, high quality provider to promote Access and Value, consistent with the SHCC’s own core values and Basic Principles guiding the development of the *SMFP*.

SUMMARY

Wilmington Health supports the standard methodology for cardiac catheterization equipment found in Chapter 17A of the *Proposed 2023 SMFP*, which determines need in Brunswick and New Hanover counties separately, using two distinct need methodologies. While the SHCC may determine that a special need exists in Brunswick County for a fixed cardiac catheterization unit, Wilmington Health does not believe that it should remove the need identified by the methodology for New Hanover County for the reasons described above. Wilmington Health strongly believes that the development of an additional unit of cardiac catheterization equipment in New Hanover County will ensure that patients have adequate access to these services, particularly when it may provide the opportunity to enhance competition, lower costs and expand access, consistent with the Basic Principles. Wilmington Health believes that the standard methodology is sound and appropriately reflects the need for another unit of cardiac catheterization equipment in the service area at this time. On that basis, the SHCC should deny NH New Hanover's petition.

Thank you.