



**Comments on Competing Applications for One
Additional Fixed Cardiac Catheterization Unit in
New Hanover County**

October 2, 2023

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submitted by

Wilmington ASC, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Wilmington ASC, LLC (“Wilmington Health”) submits the following comments related to the competing application submitted by Novant Health New Hanover Regional Medical Center (“Novant”, “NHNHRMC”, Project ID # O-012415-23) to develop an additional unit of fixed cardiac catheterization equipment in New Hanover County in response to the need determination identified in the *2023 State Medical Facilities Plan*. To facilitate the Agency’s review of these comments, Wilmington Health has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria creating the non-conformity in the Novant application.

GENERAL COMMENTS

As the only existing cardiac catheterization provider in New Hanover County, the need determination for one additional unit of equipment was based on the utilization of Novant’s existing equipment. In particular, as shown in the *2023 SMFP*, the need determination in a county such as New Hanover, which has existing fixed equipment, is based on Methodology 1, which uses the utilization of that equipment to project need for additional equipment. As such, the only method through which another provider in the county can apply for fixed cardiac catheterization equipment is through a need determination generated by Methodology 1, as Wilmington Health is doing in this review.

Of note, Novant is not only the sole provider of cardiac catheterization services in New Hanover County, but is also the only provider of full-time, fixed catheterization services along the coast between New Bern, North Carolina and Little River, South Carolina and inland to Lumberton in Robeson County. In that context, in 2022, Novant petitioned¹ to have the need determination for one additional unit of cardiac catheterization equipment removed for New Hanover County in lieu of a need determination in Brunswick County, where Novant currently also serves as the only provider of cardiac catheterization equipment, albeit using mobile equipment. In response to Novant’s petition, Wilmington Health commented to the SHCC² that it believed there was a need for another unit of fixed cardiac catheterization equipment in New Hanover County, and that in allocating such a need, there was a tremendous opportunity to enhance competition and lower costs of providing cardiac catheterization services. With these two viewpoints to consider, the SHCC denied the Novant petition and included the need determination for New Hanover County in the *2023 SMFP*, as well as one for a shared unit in Brunswick County, for which Novant has indicated in the New Hanover application that it intends to apply.

While Novant includes steps in its utilization methodology for the New Hanover application that account for the presumed approval of its pending application for a fixed cardiac catheterization unit in Brunswick County (the submission deadline for this need determination is October 16, 2023; see page 309 of the *2023 SMFP*), there is no acknowledgement nor discussion of its 2022 Summer Petition to remove the need

¹ <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T03-PetitionNHNewHanoverCardiacCath.pdf>

² <https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/T03a-WilmingtonHealth.pdf>

determination in New Hanover County. This omission is relevant to the New Hanover application because in its petition, Novant argued quite clearly that the need for additional cardiac catheterization resources in New Hanover County is based on patients from Brunswick County, not New Hanover County.

Indeed, Novant included historical data in its petition that calculated over 52 percent of diagnostic cardiac catheterizations at NHHHRMC were performed on Brunswick County patients, while 23 percent of interventional catheterizations at NHHHRMC were performed on Brunswick patients.³ Further, Novant stated in its petition that upon development of fixed cardiac catheterization services in Brunswick County and the subsequent shift of patients, NHHHRMC will be able to “accommodate the remaining cardiac catheterization procedures in its six [existing and approved] cardiac catheterization labs.”⁴ According to the petition filed in 2022, the ability to develop a fixed catheterization laboratory in Brunswick County, which is now pending through the upcoming need determination, would eliminate the need for Novant to apply for additional cardiac catheterization equipment in New Hanover County. In this New Hanover application, Novant does not explain why it has reversed course just one year later and now believes it needs additional cardiac cath resources in New Hanover County. In fact, the application is completely silent as to the petition, the reasons for Novant’s change of heart, or any factors that have materially changed since it filed a petition claiming that the allocation of fixed cardiac catheterization equipment in Brunswick County would obviate Novant’s need for another unit of equipment in New Hanover County.

As such, and based on the comments below, Wilmington Health does not believe that Novant has demonstrated the need for the proposed project. Moreover, since Novant indicated that the development of a fixed cardiac catheterization program in Brunswick County and the shift of patients to that site would allow its existing six units to suffice, it is clear that Wilmington Health can develop its proposed project, expanding access to cardiac catheterization services in a high quality, lower cost environment, without negatively impacting Novant’s ability to continue serving patients. In particular, Novant’s current application, which would develop a new cardiac catheterization laboratory at its community hospital in Scotts Hill, does not propose to provide 24/7 coverage for emergencies, such as STEMI patients, and as such, would serve scheduled outpatients, like Wilmington Health. Given the clear cost savings and enhanced competition available through the approval of Wilmington Health’s proposed project, the Novant application should be denied.

APPLICATION-SPECIFIC COMMENTS

Even if one does not consider Novant’s previous claims that it has no need for additional cardiac catheterization capacity in New Hanover County, the Novant application contains methodological flaws that understate what would be a reasonable shift of Brunswick County patients from NHHHRMC to the future Brunswick County equipment. As a result of these errors, the application is not conforming with multiple statutory and regulatory review criteria, as noted below, and the application should not be approved. In particular, the errors in the Novant application include:

- Failure to demonstrate that the utilization projections are based on reasonable and adequately supported assumptions; and,
- Failure to demonstrate that the proposed project would not result in unnecessary duplication of existing services.

³ See Novant petition, p. 3.

⁴ Ibid.

These issues are discussed in more detail below.

1. The Novant application uses misleading assumptions to underestimate the volume that would shift to a Brunswick County cardiac catheterization facility, resulting in overstated volume for Novant’s proposed New Hanover project.

Beginning on page 118 of its application, Novant describes its process for calculating the number of cases that will shift to Novant Health Brunswick Medical Center (“NHBMC”) if it is approved to develop a shared fixed unit of cardiac catheterization equipment in Brunswick County. Novant assumes that some percentage of patients residing in the NHBMC service area (defined as Brunswick and Columbus counties) will continue to have cardiac catheterizations performed at NHHHRMC after cardiac cath services begin at NHBMC. However, Novant makes the false assumption that the current percentage of admitted inpatients from Brunswick and Columbus counties at NHHHRMC is a valid comparison for this step, concluding that the use of Diagnosis Related Groups (“DRGs”) “reasonably estimates the proportion of patients from Brunswick and Columbus counties choosing each hospital for services both hospitals routinely provide.”⁵ Following this logic, Novant applies the following percentages for the shift of patients to the NHBMC cardiac cath service:

Patient Destination for DRGs for which Both Hospitals >=12 Discharges

	NHHHRMC	NHBMC
Brunswick County residents	47%	53%
Columbus County residents	81%	19%

Source: Novant application, p. 119.

This methodology results in NHHHRMC retaining 47 percent of the current volume of patients from Brunswick County and 81 percent of the current Columbus County volume before adjusting for cardiac cath procedure codes that are appropriate for the Brunswick facility.⁶ However, Novant does not explain why inpatient-based DRG codes were used in this step for what is primarily an outpatient service. It is reasonable to assume that had Novant compared the percentages of Brunswick County patients with outpatient-based procedure codes at both facilities, the percentage of the total at NHHHRMC would be much lower, as healthcare consumers often cite the proximity to home and travel considerations when choosing a facility for elective ambulatory procedures that do not require hospitalization. An April 2023 survey of more than 4,000 U.S. residents found that location was the second-most important factor in the choice of provider, with 31 percent of respondents saying they would not travel more than 15 minutes to a facility for outpatient procedures.⁷

Moreover, this simplistic approach fails to consider that DRGs include many different types of patients and procedures; as such, the percentage of patients in a particular DRG that received

⁵ Novant application, p. 119.

⁶ Ibid. Novant assumes that only a smaller subset of procedures that are clinically appropriate for a community hospital will shift to NHBMC, with the remainder continuing to be performed at the NHHHRMC main campus.

⁷ JLL Research, 2023 Patient Consumer Survey, <https://www.us.jll.com/en/trends-and-insights/research/2023-patient-consumer-survey>. Accessed August 24, 2023.

care in New Hanover County is certainly influenced by the specific procedure or the patient’s underlying condition that may have required a higher level of care. The percentage of patients that were admitted for some number of inpatient care days at NHHNHRMC would thus logically be higher compared to those that would choose to have an outpatient procedure performed closer to home once the service is available to them on a full-time basis. The flaw in Novant’s assumption is demonstrated by the fact that a higher percentage of inpatients from Columbus County—which is contiguous to Brunswick County, not New Hanover County—travel beyond Brunswick County into New Hanover County for care (81 percent versus 19 percent, as shown above). This assumption, which clearly does not have a reasonable basis, was selected to assure that Novant does not reassign too many Brunswick and Columbus County residents to a facility closer to home, and instead introduces a means for Novant to project need for additional catheterization equipment in both counties. This is a direct contradiction of the statement in Novant’s petition that the development of the Brunswick County cardiac catheterization equipment would eliminate the need for it to obtain more equipment in New Hanover County.

Using these understated percentages to calculate the shift in volume, Novant estimates the following volumes of cardiac catheterization procedures at NHBMC:

Projected Volume at NHBMC’s Proposed Cath Lab, July 2025 – December 2029

	2025 Jul – Dec	26 Jan-Oct 14th	26 Oct 15th-Dec 31st	CY2027	CY2028	CY2029
Diagnostic Cath Cases	301	490	133	643	665	687
Therapeutic Cath Cases	187	304	83	400	413	427
Total Cath Cases	489	794	216	1,043	1,078	1,113
Diagnostic-Equivalent Cases	629	1,022	278	1,343	1,388	1,433

Source: Novant application, p. 120.

Novant estimates the cardiac catheterization unit at NHBMC will perform a total of 1,113 cases in Project Year 3, or 1,433 diagnostic equivalent cases. However, if these shift assumptions are adjusted using a more reasonable estimation of cases that will stay in Brunswick, that is, one that is consistent with the position in its petition to remove the need determination in New Hanover County, the utilization would be significantly higher for the unit in Brunswick. To make more reasonable assumptions, the first step is to revise Novant’s estimation of the percentage of cases retained by NHHNHRMC in Step 4B of its methodology to depict a more realistic shift based on ambulatory cases. This results in NHBMC receiving 75 percent of cardiac cath cases for Brunswick patients that currently receive care at NHHNHRMC, rather than 53 percent in Novant’s model. It is also reasonable to assume this percentage will be lower for Columbus County residents, from 81 percent to 50 percent.

**Table 1: Novant Health Brunswick
Restated Shift in Patient Destination – Ambulatory Cases**

	<i>NHHNHRMC</i>	<i>NHBMC</i>
Brunswick County residents	25%	75%
Columbus County residents	50%	50%

Using these revised estimates and multiplying them by the same percentages of appropriate codes for a community hospital without open heart surgery services that Novant calculates in Step 4A, the volumes of cardiac catheterizations at NHHHRMC that would shift to NHBMC are restated in the following table:

**Table 2: Novant Health Brunswick
Restated Cardiac Catheterization Procedures**

	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
Diagnostic Cath Cases	993	1,026	1,059
Therapeutic Cath Cases	619	639	661
Total Cath Cases	1,611	1,665	1,720
Diagnostic-Equivalent Cases	2,076	2,144	2,215
Variance in Diagnostic-Equivalent Cases	+733	+756	+782

With the recalculation of these shifts in cases to the Brunswick facility, NHBMC would gain 607 additional cardiac catheterization cases in Project Year 3 (372 diagnostic cases and 234 interventional cases), representing 782 diagnostic-equivalent cases. Stated another way, NHHHRMC has overstated utilization in each of its three project years and has erroneously included 607 additional cardiac catheterization cases in its financial projections. With these adjustments, NHHHRMC would more reasonably be expected to perform 782 fewer diagnostic-equivalent cases in PY3, or 6,575 total diagnostic-equivalents. This number is smaller than the number performed in CY 2022 at NHHHRMC (7,178 per page 118), which is consistent with a more reasonable shift of patients to Brunswick and the statements Novant made in the petition that it would not need additional capacity in New Hanover County given the need in Brunswick.

As a result of this issue, the Novant application is non-conforming with Criteria 3 and 5.

2. The Novant application fails to account for the diagnostic catheterizations that it stated would shift to its approved PET scanner.

Novant failed to account for the development of an additional PET scanner, which has been approved to be located at its Scotts Hill hospital (Project ID # O-12143-21). In that application, Novant referenced the use of PET for diagnosing cardiovascular disease. In particular, cardiac PET is useful in lieu of other types of tests for cardiovascular disease, including SPECT and diagnostic cardiac catheterizations. According to the *Proposed 2024 SMFP*, NHHHRMC performed 3,372 diagnostic cardiac catheterization procedures in 2022, which accounted for the majority (60.5 percent) of its total procedures. In its 2021 application, which the Agency approved, Novant wrote the following concerning the cardiac imaging capabilities of its PET scanner at Scotts Hill:

Introduction of Cardiac PET

This project will be the first to introduce cardiac PET to the service area. There is no provider in the service area that is providing cardiac PET. Currently, patients have to travel to Raleigh if they are in need of cardiac PET. Cardiac PET has been recognized for its efficacy in imaging heart conditions, particularly for obese patients for whom imaging quality is limited with the alternative SPECT imaging. Compared to SPECT imaging, cardiac PET offers lower radiation exposure, fewer artifacts, improved spatial resolution, and improved diagnostic performance in evaluating myocardial perfusion.¹¹ Medicare, Medicaid, and all other payors now cover this service in recognition of the benefits of this service and even the potential cost saving associated with some potential reduction in diagnostic cardiac cath using cardiac PET to determine whether a patient would benefit from percutaneous coronary intervention ("PCI") or coronary artery bypass graft ("CABG") surgery.¹² As the regional tertiary provider of cardiac services for the service area and region, NHRMC has a large base of patients who would benefit from access to cardiac PET services.

NHNHRMC Scotts Hill PET Scanner CON Application, Project ID # O-12143-21, page 40. Highlighting added.

The application includes the discussion of cardiac PET in demonstrating need for its proposal, as noted in the following excerpts:

The main uses for the test include but are not limited to:

- Screening for cardiovascular disease among those who are symptomatic or who have associated risk factors such as family history or high cholesterol.
- To monitor the condition of the heart and the success of treatment in those who have been previously diagnosed with CAD for certain patients.
- To further evaluate previously detected blockages and determine a patient's candidacy for coronary stents or bypass surgery for certain patients.
- To determine the extent of tissue damage and scarring following a heart attack and identify the most appropriate treatment method.

NHNHRMC Scotts Hill PET Scanner CON Application, Project ID # O-12143-21, page 72. Highlighting added.

The use of PET for cardiac imaging is an evolving application for the technology with new clinical implications being rapidly developed by researchers. With the increasing support and recommendations, the modality is receiving, it will be used more often as an initial test to diagnose a variety of chronic heart conditions. This increase in demand will further increase the need for expansion of PET capacity to meet the needs of service area patients.

NHNHRMC Scotts Hill PET Scanner CON Application, Project ID # O-12143-21, page 73. Highlighting added.

Thus, in its application to develop a new PET scanner at the same location at which it is now proposing an additional unit of catheterization equipment, Novant touted the benefits of cardiac PET and the potential to save costs through the "reduction in diagnostic cardiac cath using cardiac PET." In this application to add another unit of cath equipment, Novant fails to acknowledge that it was approved for another PET scanner because it expected patients to have cardiac PET instead of a diagnostic cardiac cath procedure. Moreover, the PET application expressly stated that the cardiac PET capabilities would all be at the Scotts Hill campus:

existing PET providers. Additionally, all cardiac PET volume will be served on the Scotts Hill Campus.

NHNHRMC Scotts Hill PET Scanner CON Application, Project ID # O-12143-21, page 78. Highlighting added.

While Novant was approved for an additional PET scanner at its Scotts Hill hospital in part because of the need to perform cardiac PET in lieu of diagnostic cardiac catheters and other tests, it failed to account for the impact of the shift of diagnostic catheters to its PET scanner, and therefore has overstated its cardiac cath utilization.

For these reasons, the Novant application is non-conforming with Criteria 3 and 5.

3. The Novant application does not demonstrate that the addition of a fixed cardiac catheterization unit on the NHHHRMC license is needed or that it is the most effective or least costly alternative.

In Section E of its application, Novant considers only two alternatives to its proposed project: 1) maintain its current inventory of six existing and approved cardiac catheterization labs at the NHHHRMC campus, or 2) add a seventh catheterization unit on the NHHHRMC license. Neither of the alternatives proposed by Novant appear to factor in the presumed approval of its Brunswick County application for a shared fixed cardiac cath unit, and subsequent decrease in volume at NHHHRMC once more than 1,000 cases shift to the Brunswick location. Indeed, the introduction of cardiac catheterization services in Brunswick County will in effect keep volume flat at NHHHRMC, despite population growth in New Hanover County. Using the revised shift in cardiac catheterization patients from NHHHRMC to the future Brunswick facility (shown in Table 2 above), utilization at NHHHRMC for actual CY 2022 and projected project years CY 2027-2029 is shown as follows:

**Table 3: Novant Health New Hanover Regional Medical Center
Cardiac Catheterization Utilization**

	<i>CY 2022</i>	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
Diagnostic Cath Cases	3,029	2,854	2,949	3,047
Therapeutic Cath Cases	2,371	1,889	1,952	2,016
Total Cath Cases	5,400	4,744	4,901	5,063
Diagnostic-Equivalent Cases	7,178	6,160	6,365	6,575
Number of Cath Units Used to Perform Historical/Projected Cases	5	7	7	7
Average Utilization per Cath Unit	1,436	880	909	939

Source: Novant application p. 126; Table 2.

The number of diagnostic equivalent cases is projected to decrease 8.4 percent, from 7,178 total diagnostic-equivalent cases in CY 2022 to 6,575 cases in Project Year 3. Combined with the pending addition of the approved but undeveloped fixed cardiac catheterization unit from the 2021 review (Project ID # O-12112-21) and the potential addition of a seventh unit in the 2023 review, NHHHRMC's average utilization would be nearly 35 percent lower in Project Year 3 than in the most recent year. Novant does not provide an explanation of why it cannot accommodate the reduced demand at its New Hanover County facilities using the existing and approved resources.

Moreover, even assuming that Novant's projected shifts to Brunswick are reasonable, (that is, rejecting the adjustments made in the narrative above), **it projects only 179 additional total diagnostic-equivalent cases in PY3 compared to CY 2022, yet it proposes two additional cardiac**

catheterization units to accommodate those cases. While Novant is approved for a sixth unit from the 2021 SMFP, that unit has not yet been implemented. Thus, the volume reported for CY 2022 was actually performed on only five units, which, as shown in Table 3 above, is 1,436 diagnostic equivalents per unit. Thus, with the implementation of its approved unit, and accounting for the shift of cases Novant projects to its pending proposed unit in Brunswick County, there is no need for an additional seventh unit at Novant.

**Table 4: Novant Health New Hanover Regional Medical Center (License)
Cardiac Catheterization Utilization with Existing/Approved Units**

	CY 2022	PY1	PY2	PY3
Diagnostic Cath Cases	3,029	3,204	3,310	3,419
Therapeutic Cath Cases	2,371	2,108	2,178	2,250
Total Cath Cases	5,400	5,312	5,488	5,669
Diagnostic-Equivalent Cases	7,178	6,893	7,121	7,357
Existing and Approved Cath Units (excluding proposed)	5	6	6	6
Average Utilization per Cath Unit	1,436	1,149	1,187	1,226

Source: Novant application, pages 118 and 121.

As shown in Table 4, across its license in New Hanover County, Novant projects to perform only 179 additional diagnostic-equivalent cases by PY3 ($7,357 - 7,178 = 179$). As it stands currently, without approval of the proposed project, Novant would have six units of equipment on which to perform those cases, yet it proposes to acquire a seventh in this application, for a marginal increase in additional cases.

This issue is also shown in Novant’s application, page 125, which demonstrates that it projects to perform 777 fewer diagnostic-equivalent cases in PY3 at its main campus compared with CY 2022 ($7,178 - 6,401 = 777$), yet it will have the sixth (approved but not yet developed) cath unit to accommodate significantly fewer cases.

Given this analysis based on Novant’s own projections, Novant clearly failed to consider its most effective option: relocating an existing cath unit from its inventory at NHHHRMC to the Scotts Hill campus. Relocating an existing cardiac catheterization unit would likely result in lower capital costs as well as operational costs, as there would be opportunities to transfer clinical staff from the main campus to Scotts Hill.

Novant may certainly contend that its projected utilization demonstrates conformity with the performance standards; however, the 900 diagnostic-equivalent performance standard is not the full capacity of a unit of equipment but is only 60 percent of the defined capacity of 1,500 diagnostic-equivalents (see 2023 SMFP, page 300, Assumption 2), and conformity with the rule does not demonstrate need or otherwise conformity with Criterion 3. As shown in Table 4 above, with the projected shift to Brunswick County, using Novant’s own assumptions, its approved six cath units will be operating at a lower per unit threshold than they are currently, and there is simply no need for the proposed seventh cath unit at NHHHRMC.

Based on the reduction in projected volume, the pending development of an approved cath unit at NHHRMC, and its failure to consider more effective alternatives to the proposed project, Novant's application is non-conforming with Criteria 3 and 4.

COMPARATIVE ANALYSIS FOR FIXED CARDIAC CATHETERIZATION UNIT

As noted above, Wilmington Health believes the Novant application is non-conforming with multiple statutory and regulatory review criteria and should not be approved. Further, Wilmington Health believes that its application represents a more compelling project in that it will enhance competition in New Hanover County while offering patients an alternative to hospital-based cardiac catheterizations, maximizing accessibility in a freestanding location, and lowering costs for payors and consumers. The Wilmington Health (Project ID # O-012416-23) and the Novant (Project ID # O-012415-23) applications both propose to develop an additional fixed cardiac catheterization unit in response to the 2023 SMFP need determination for New Hanover County. Given that both applicants propose to meet the need for New Hanover County, only one can be approved. To determine the comparative factors that are applicable in this review, Wilmington Health examined recent Agency findings for competitive cardiac catheterization reviews. The Agency completed a similar review of competing applications for a fixed cardiac catheterization unit in New Hanover County in 2021. Based upon that analysis and the facts and circumstances of the competing applications in this review, Wilmington Health believes the following comparative factors will be helpful to the Agency in its review:

- Conformity with Review Criteria
- Competition (Patient Access to a New Provider)
- Access by Service Area Residents
- Geographic Accessibility
- Scope of Services
- Access by Underserved Groups
 - Projected Charity Care
 - Projected Medicare Patients
 - Projected Medicaid Patients
- Projected Average Net Revenue per Procedure
- Projected Average Operating Expense per Procedure
- Access to Lower Cost Services

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

Conformity with Review Criteria

As noted above, the Novant application is non-conforming with at least Criteria 3, 4 and 5, while the Wilmington Health application conforms with all review criteria.

Competition

In the 2021 Agency review, the analyst noted that the “introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients.”⁸ In the 2021 review, Novant was an existing provider of cardiac catheterization services in New Hanover County, while Wilmington Health had no cardiac cath services in New Hanover County. The Wilmington ASC project was therefore found to be more effective for this factor. The situation is identical for this current review, with Novant controlling all six operational or approved cardiac catheterization

⁸ 2021 New Hanover County Cardiac Cath Review, p. 58.

units in New Hanover County, while Wilmington Health has none. The Agency should again deem the Wilmington Health project to be more effective for this factor.

Access by Service Area Residents

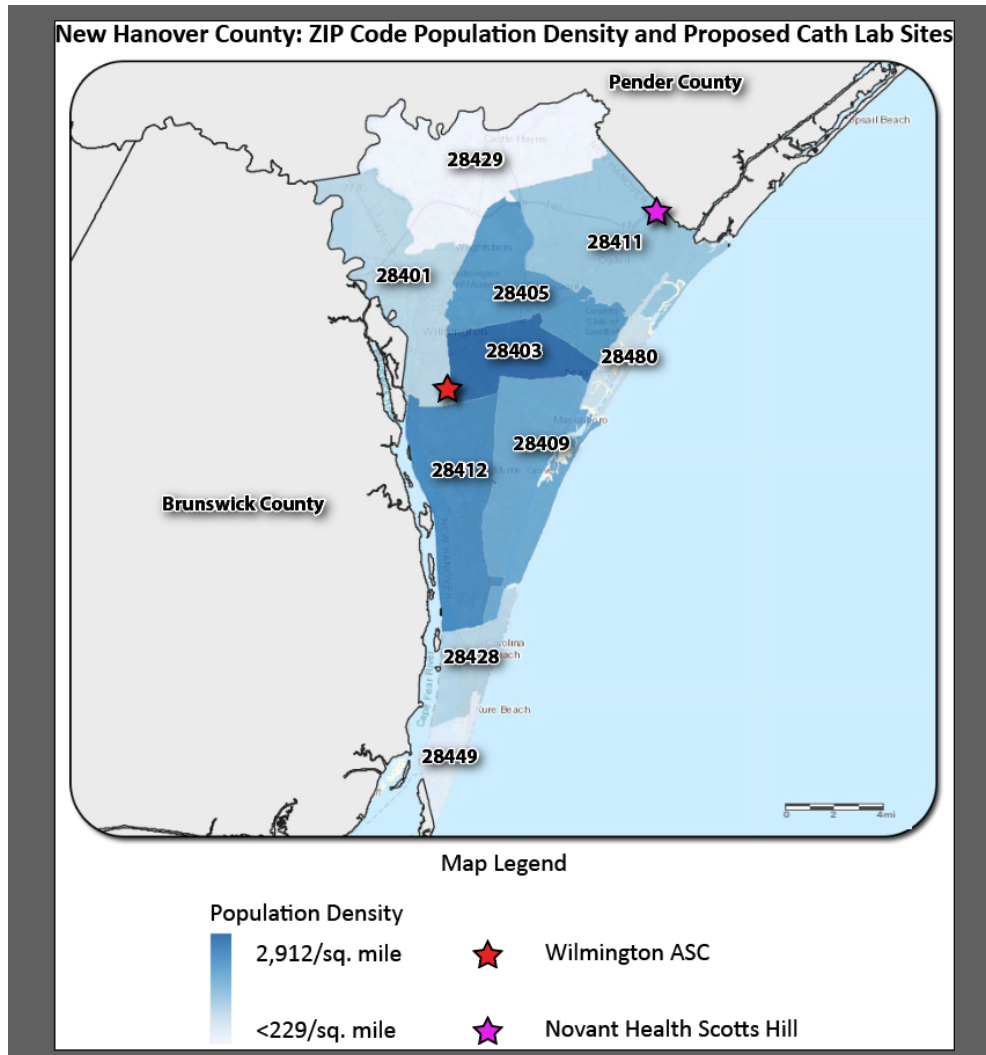
Novant projects that the new unit of equipment will serve 350 patients from New Hanover County in CY 2029, the third year of the project.⁹ The Wilmington Health project estimates it will serve 347 patients from New Hanover County in CY 2028, the third project year.¹⁰ This negligible difference in patients served indicates that both applicants are equally effective for this factor. However, it should be noted that although the project years in the comparison are the same, the *time period* is one year later for Novant's calculation. This incorporates an additional year of population growth into the number of New Hanover County patients served. Assuming that Wilmington Health's projected patient volume will continue to increase, it would reasonably be expected to serve a higher number of New Hanover County patients in CY 2029 compared to Novant. Alternatively, comparing the same year, CY 2028, Wilmington Health projects to serve 347 patients from New Hanover County while Novant projects to serve 338. Finally, while the Agency does not typically compare timelines for project development as a separate factor, Wilmington Health is projecting to begin serving patients, including New Hanover County patients, more than one year earlier than Novant. Specifically, Wilmington Health projects to serve patients beginning June 2, 2025, while Novant projects to begin operating on October 15, 2026, 16 months later. This difference in timing means that Wilmington Health will offer expanded access to New Hanover County patients much sooner than Novant, which, in this particular case, should be considered under this comparative factor. These analyses clearly demonstrate that Wilmington Health is the more effective applicant regarding this factor.

Geographic Accessibility

The proposed Wilmington ASC location is in one of the most densely populated ZIP codes in the county, optimizing the number of patients within a convenient travel distance of the facility. Wilmington Health's location at 1201 Glen Meade Road in Wilmington is close to the most populous areas of New Hanover County and is centrally located to maximize access for residents from all parts of the county. The Scotts Hill campus in Novant's proposed project in northeast New Hanover County is located at the far northern boundary of New Hanover County, approximately 13 miles north of Wilmington and adjacent to the Pender County border. Indeed, Novant's Scotts Hill campus is more accessible to Pender County than much of New Hanover County, as shown on the following map. While there are no fixed cardiac catheterization services in the Scotts Hill community, a location in central New Hanover County will better serve the entirety of New Hanover County, particularly as the first and only freestanding ASC-based cardiac catheterization unit. For this reason, the Wilmington Health application is more effective regarding this factor.

⁹ Novant application, p. 38.

¹⁰ Wilmington Health application, p. 40.



Source: Esri.

Scope of Services

Although the Wilmington Health project represents an ASC-based fixed cardiac catheterization service and Novant's proposed project is hospital-based, both projects will offer a narrower range of procedures than cardiac catheterization programs located at hospitals with open heart surgery capabilities. As noted in its application, the Wilmington Health project will perform only diagnostic and elective interventional cardiac catheterization procedures that are included in CMS's most current list of Medicare-covered ASF procedures for patients that are deemed appropriate for a freestanding setting. Novant states that it will perform a limited set of procedures at its Scotts Hill cath lab, based on the constraints at the campus regarding lack of on-site open heart surgery.¹¹ Both Wilmington Health and Novant will perform the same diagnostic and interventional (therapeutic) catheterizations, including angioplasty and stent placement, that are appropriate for facilities without on-site open heart surgery backup. Procedurally, there is little difference between the two applications, and the two projects are thus equally effective.

¹¹ Novant application, p. 119.

Historical Utilization

Novant operates five fixed cardiac catheterization units in New Hanover County and is approved to add one additional unit. Wilmington Health has no existing cardiac catheterization units in New Hanover County. In the 2021 review, the Agency stated that the existing provider with historical utilization was more effective because it generated the need and “has a greater need... in order to serve its projected patients.”¹² However, subsequent to the Findings in the 2021 review, the Agency has since ruled that a comparison of this factor between existing and new providers is inconclusive: in the 2022 Wake County OR Review, the Agency evaluated comparative factors for six competing applicants for OR need. KM Surgery Center and Oakview ASC were both new applicants for additional ORs that were in the joined review with four providers that had existing Wake County surgical services. The Agency concluded that because KM Surgery Center and Oakview ASC had no historical utilization, “a comparison [of this factor] cannot be effectively evaluated.”¹³ Further, it is aware that the Agency typically finds this factor inconclusive when one of the providers has not historically provided the service in its facility; thus, Wilmington Health believes that a similar conclusion is valid in this review.

Access by Underserved Groups

Projected Charity Care – This factor should not be applicable for the review due to differences in the financial projections. In the Findings for the 2021 New Hanover County Cardiac Cath Review, the Agency concluded that “... differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants may impact the averages shown in the table above. Therefore, the result of this analysis is inconclusive.”¹⁴ Wilmington Health’s project will perform cardiac catheterizations in an ASC facility, with significant differences from a hospital-based program as Novant has proposed. Without being able to compare applications with similar reimbursement schedules and operational structures, the factor is inconclusive and should therefore be excluded from the analysis.

Projected Medicare – The following table compares access by Medicare patients in Project Year 3 for both applicants. Wilmington Health has a higher volume of Medicare patients and percentage of Medicare patients, while Novant has a higher amount of gross revenue for Medicare patients and higher percentage of total gross revenue represented by Medicare patients. Therefore, both applicants are equally effective regarding access by Medicare patients. However, this factor again compares reimbursement for two different facility types, with corresponding differences in revenue calculations. The 2021 New Hanover County Cardiac Cath Review Findings stated that projected Medicare access was not a valid comparative factor due to “... differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants.”¹⁵ This factor should not be applicable for the review due to differences in the financial projections based on the different types of facilities proposed.

¹² 2021 New Hanover County Cardiac Cath Review, p. 54.

¹³ 2022 Wake County Acute Care Bed and OR Review, p. 212.

¹⁴ 2021 New Hanover County Cardiac Cath Review, p. 57.

¹⁵ Ibid.

Medicare Access by Applicant – Project Year 3

	<i>Wilmington Health</i>	<i>Novant</i>
Medicare Gross Revenue	\$3,732,387	\$24,463,807
Medicare as a % of Total Gross Rev	59%	64%
Medicare Patients	494	492
Medicare Patients as a % of Total	65%	64%

Source: Section Q, Forms F.2b and Form C; Section L.3

Projected Medicaid – As shown in Form F.2b for cardiac catheterizations, Wilmington Health expects to serve Medicaid patients. Further, as discussed in the Form F.2b assumptions, while not currently reimbursed by North Carolina Medicaid, Wilmington Health expects that cardiac catheterizations performed in an ASF will eventually be reimbursed by NC Medicaid. However, out of an abundance of caution, Wilmington Health’s financial projections assume no reimbursement for Medicaid patients. In the 2021 New Hanover County Cardiac Cath Review, the Agency’s analysis implied that Wilmington Health would not serve Medicaid patients because of this assumption. To be clear, Wilmington Health projects to serve Medicaid patients regardless of reimbursement.

The following table compares access by Medicaid patients in Project Year 3 for both applicants. As discussed with the two previous underserved groups, differences in the types of facilities proposed by Wilmington Health and Novant will impact the averages shown in the table below. Therefore, the result of this analysis is inconclusive.

Medicaid Access by Applicant – Project Year 3

	<i>Wilmington Health</i>	<i>Novant</i>
Medicaid Gross Revenue	\$90,036	\$1,003,914
Medicaid as a % of Total Gross Rev	1.4%	2.6%
Medicaid Patients	12	20

Source: Section Q, Forms F.2b and Form C; Section L.3

Projected Average Net Revenue per Procedure

The following table summarizes total net revenue and average net revenue per procedure for both applicants. The Wilmington Health application is more effective for this factor.

Average Net Revenue per Procedure – Project Year 3

	<i>Wilmington Health</i>	<i>Novant</i>
Total Net Revenue	\$2,710,564	\$7,470,485
Cardiac Catheterization Procedures	843	763
Average Net Revenue per Procedure	\$3,215	\$9,791

Source: Section Q, Forms F.2b and Form C; Section L.3

As noted previously, both applications propose the same service, cardiac catheterizations, and both propose diagnostic and interventional (therapeutic) procedures appropriate for a facility without on-site open heart surgery. While the Agency has previously found this factor to be inconclusive when the specialties proposed were different (such as for operating room proposals for different surgical specialties), both applications propose diagnostic and interventional cardiac catheterization procedures. As such, the differences in revenue are based largely on the difference between hospital-based reimbursement and freestanding ASC reimbursement, and the proposal by Wilmington Health is more effective with respect to average net revenue per procedure.

Projected Average Operating Expense per Procedure

The following table summarizes total operating expenses and average operating expense per procedure for both applicants. Wilmington Health has an average operating expense of \$2,143, less than one-half the amount for Novant (\$5,614). The Wilmington Health application is more effective for this factor.

Average Operating Expense per Procedure – Project Year 3

	<i>Wilmington Health</i>	<i>Novant</i>
Total Operating Expense	\$1,806,868	\$4,283,754
Cardiac Catheterization Procedures	843	763
Average Operating Expense per Procedure	\$2,143	\$5,614

Source: Section Q, Forms F.3b and Form C; Section L.3

As noted previously, both applications propose the same service, cardiac catheterizations, and both propose diagnostic and interventional (therapeutic) procedures appropriate for a facility without on-site open heart surgery. While the Agency has previously found this factor to be inconclusive when the specialties proposed were different (such as for operating room proposals for different surgical specialties), both applications propose diagnostic and interventional cardiac catheterization procedures. As such, the differences in operating expenses are based largely on the difference between hospital-based expenses and freestanding ASC expenses, and the proposal by Wilmington Health is more effective with respect to average operating expense per procedure.

Access to Lower Cost Outpatient Services

The Novant project proposes to locate fixed cardiac catheterization services in a hospital facility on the NHHHRMC license, while Wilmington Health will offer cardiac catheterization services in an ASF setting. CMS reimburses a lesser amount for the same cardiac catheterization procedures when performed in an ASF versus a hospital. As shown in the two previous comparative factors, Wilmington Health projects much lower average operating expenses and net revenue, despite having a higher total volume of cardiac catheterization procedures than Novant. Wilmington Health is thus the more effective applicant for offering patients a lower cost option for the provision of outpatient cardiac cath services.

Comparative Analysis Summary

The following table summarizes the comparative factors and rankings for each applicant. Wilmington Health is the only applicant that is conforming with all statutory and regulatory review criteria and is the more effective alternative for five factors: Competition; Geographic Accessibility; Average Net Revenue per Procedure; Average Operating Expense per Procedure; and Access to Lower Cost Services.

<i>Comparative Factor</i>	<i>Wilmington Health</i>	<i>Novant</i>
Conformity with Review Criteria	Yes	No
Competition	More Effective	Less Effective
Access by Service Area Residents	Equally Effective	Equally Effective
Geographic Accessibility	More Effective	Less Effective
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	Inconclusive	Inconclusive
Access by Charity Care	Inconclusive	Inconclusive
Access by Medicare	Inconclusive	Inconclusive
Access by Medicaid	Inconclusive	Inconclusive
Average Net Revenue per Procedure	More Effective	Less Effective
Average Operating Expense per Procedure	More Effective	Less Effective
Access to Lower Cost Outpatient Services	More Effective	Less Effective

SUMMARY

Wilmington Health believes that its application is the most effective alternative for the unmet need for fixed cardiac catheterization services in New Hanover County. The Wilmington Health application is also the only application that fully conforms with all applicable statutory and regulatory review criteria. As such, Wilmington Health's proposal should be approved by the Agency.