Comments Submitted by Novant Health in Opposition to Project ID# O-012416-23, Wilmington ASC's Application to Acquire One Unit of Cardiac Catheterization Equipment

Under N. C. Gen. Stat. § 131E-185, Novant Health ("NH") and Novant Health New Hanover Regional Medical Center, LLC ("NHNHRMC") submit these comments opposing the application filed by Wilmington ASC, LLC ("WASC" or "the applicant") to acquire a cardiac catheterization ("cardiac cath") unit in New Hanover County, in response to the need determination in the 2023 SMFP, Table 17A-4, page 308. WASC's application (Project ID #O-012416-23) is non-conforming with several CON criteria and with the performance standard and must be denied. NH's application for a cardiac catheterization laboratory ("cath lab") at the NH Scotts Hill campus of NHNHRMC (Project ID #O-012415-23) is conforming with all applicable CON criteria and with the performance standard. A comparative analysis shows the NH application is a more effective alternative than the WASC application. The NH application should be approved and the WASC application should be denied.

Summary

The 2023 SMFP has a need for one unit of fixed cardiac catheterization equipment in New Hanover County. Wilmington ASC and Novant Health each applied for one unit of equipment pursuant to the need determination. These comments include discussion and argument regarding whether, in light of the material contained in the WASC application and other relevant factual material, the WASC application complies with the relevant review criteria, plans and with the performance standard.[1] These comments show:

- WASC has not provided reasonable or adequately supported volume projections. These comments show that WASC has not shown an interventional cardiologist will be available to provide the projected interventional procedures. These comments also show that the percentage of Wilmington Health physicians' cardiac catheterization procedures projected to shift to WASC is unreasonable.
- WASC has not cured the defects in its previous CON application for a cath lab, filed in 2021 (Project ID # O-12121-21). A major defect was and is insufficient staffing for the proposed cath lab and associated seven-bay pre- and post-procedure area.
- The WASC application is non-conforming with CON Review Criteria (1), (3), (4), (5), (6), (7), and (18a), and with the performance standard for fixed cardiac catheterization equipment.
- Based on additional analysis NH has done since filing its 2022 petition relating to the *2023 SMFP*,[2] there is sufficient need for another fixed unit of cath lab equipment in New Hanover County. This

[1] See N.C. GEN. STAT. § 131E-185(a1)(1)(c).

[2] See Novant Health Brunswick Medical Center Petition to the State Health Coordinating Council Adjustment to Need Determination for Shared Cardiac Catheterization for Brunswick County 2023 State Medical Facilities Plan; Novant Health New Hanover Regional Medical Center Petition to the State Health Coordinating Council Adjustment to Need Determination for Shared Cardiac Catheterization for New Hanover County 2023 State Medical Facilities Plan.

analysis was included in NH's application, and refutes WASC's assertion that any CON filed by NH is "inherently nonconforming with Criterion 3." None of the statutory criteria consider an applicant's prior position in a petition that was disapproved.

The Agency cannot approve a non-conforming application. Based on these comments, NH respectfully urges the Agency to deny the WASC application as non-conforming with the CON Review Criteria and with the performance standard. These comments also compare the two applications and show the NH application is a more effective alternative than the WASC application. If the Agency finds the WASC application conforming with all CON criteria and performance standards, the WASC application is a less effective proposal than the NH application and should be denied on that basis.

WASC Conformance with CON Review Criteria

Each statutory review criterion with which WASC is non-conforming is discussed in a separate section below, and the language of the statutory review criterion is provided at the beginning of each section.

Criterion (1)

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

The WASC application conforms to the need determination in the 2023 SMFP for one additional cath lab in New Hanover County, but it fails to conform to Policy GEN-3.

Policy GEN-3: Basic Principles

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

The WASC Application Does not Promote Safety and Quality

WASC proposed minimal staffing for its cath lab in Form H which is insufficient for a high-quality, safe cardiac catheterization program. WASC proposes one LPN to cover a seven-bad prep/recovery area.[3] One LPN cannot take care of seven patients as "they recover post-procedure to ensure patient safety."[4] An LPN has a limited scope of practice, and must be directed and supervised by a Registered Nurse (RN), physician or other person authorized by state law (See Exhibit 1).

Conscious, or moderate, sedation is routinely ordered for patients undergoing procedures in the cath lab.[5] In North Carolina, conscious sedation requires an RN level of care. The North Carolina Board of Nursing does not permit LPNs to administer conscious sedation. See Exhibit 3 (NC Board of Nursing Position Statement on Procedural Sedation/Analgesia, stating that administration of sedation/analgesia is outside the LPN scope of practice). An RN may administer moderate sedation, but the nurse may not assume other responsibilities which would leave the patient unattended, jeopardizing patient safety. See Exhibit 3. Note also that according to Form H, there will be only one RN. The sole RN cannot be assisting with cath procedures, supervising the sole LPN (see Exhibit 2 LPN Scope of Practice clarification which states LPNs must be under supervision of RN or physician), and closely monitoring pre- and post-procedure patients all simultaneously. Accordingly, the staffing that WASC proposes is deficient and will compromise patient safety. The Agency cannot approve a project that is unsafe.

This issue was also present in WASC's 2021 CON application for a cath lab in New Hanover County. While NHNHRMC brought this issue to WASC's attention in its written comments on that application, WASC has not increased its proposed staffing to provide high-quality, safe care or explained why it thinks the proposed staffing is sufficient.

WASC also did not show its understanding that ASC-based cath labs most undertake "judicious case selection" to safely perform procedures. The Society for Cardiovascular Angiography and Interventions (SCAI) is "the only professional medical society in the US dedicated solely to interventional cardiology."[6] It published the most recent "SCAI Expert Consensus Statement on Percutaneous Coronary Intervention without On-Site Surgical Backup" in January 2023.[7] According to the SCAI, "most patients with acute coronary syndromes are admitted to the hospital and therefore are not considered for procedures in ASCs." Seven comorbidities, including decompensated heart failure, valvular heart disease, respiratory compromise and any condition likely to require overnight hospitalization, should be treated in a hospital setting. According to SCAI, "the guiding principle for the physician should be to avoid cases with a significant possibility of requiring support beyond what can be readily provided in the ambulatory

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[3] WASC CON Application, Form H.

[4] WASC CON Application, Section K, p. 98.

[5] Society for Cardiovascular Angiography & Interventions. Moderate Sedation Practices for Adult Patients in the Cardiac Catheterization Laboratory (CCL). Available at: https://scai.org/moderate-sedation-practices-adult-patients-cardiac-catheterization-laboratoryccl

[6] Society for Cardiovascular Angiography & Interventions. https://scai.org/

[7] Grines, Cindy et al. SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup" *JSCAI 2 (2023)*

setting."[8] As discussed under Criterion (3), WASC's projected volume assumed 90 percent of Wilmington Health's outpatient cath lab volume for CMS-approved CPT codes will be treated at WASC. The WASC application has no documentation or other support showing a 90 percent shift to the ASC is reasonable or consistent with proper patient selection.

The WASC Application Does not Address the Needs of all Residents in the Proposed Service Area

WASC proposes to offer ASC-based cath lab services in New Hanover County. This project cannot provide services to inpatients or emergent patients who need cath lab services. WASC can only treat scheduled outpatients for one of the CPT procedure codes Medicare has approved for payment in an ASC. In Exhibit C-4.5 of its application, WASC lists the Medicare-covered cath lab procedures for an ASC. The list has thirteen CPT codes, only two of which are interventional procedures. WASC must further limit its patient population to only lower-risk patients. For more detail on the Society for Angiography & Interventional Cardiology guidance regarding which patients can properly be treated in an ASC, please see Exhibit 1 and the discussion on page 3, which is incorporated here by reference.

NH Scotts Hill would provide a wider array of cath lab procedures for a wider array of patients. Exhibit L-3 of the NH application lists 21 CPT codes and 31 ICD-10 codes NH intends to perform at the NH Scotts Hill cath lab. This list was developed by NH's HVI team, including Dr. Frederick Merine. Expressed as a percentage, WASC projects doing only 20 percent of the outpatient interventional procedures NH Scotts Hill will do. As discussed below, the volume and range of interventional procedures at WASC is limited both by having only two procedures approved for an ASC, and because Wilmington Health has only one interventionalist on staff who provided no evidence of support for this project. The Agency must carefully consider which provider in this review will offer the wider array of services to a wider array of area residents.

WASC did not adequately document the availability of interventional cardiologists to perform therapeutic cath lab procedures. Wilmington Health is the sole member of WASC and the employer of the cardiologists who will use WASC's proposed cardiac cath lab. Nowhere in its application does WASC state it will offer privileges to outside cardiologists, and the only letters of support are from Wilmington Health providers. Nowhere in its application did WASC state that Wilmington Health is recruiting more cardiologists who will perform procedures in the cath lab. The table below identifies the Wilmington Health cardiologists, their board certifications and if they provided a letter of support for the WASC application.

[8] Grines, Cindy et al. SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup" *JSCAI 2 (2023)*

Cardiologist	Board Certifications		Provided Letter of Support
Andrew Bishop, MD, FACC	Internal Medicine Cardiovascular Disease	Interventional Cardiology	**No**
Matt Janik, MD, FACC	Internal Medicine Cardiovascular Disease Nuclear Cardiology	Cardiovascular MRI Cardiovascular CT	Yes
Craig McCotter, MD, FACC, FHRS	Internal Medicine Cardiovascular Disease	Cardiac Electrophysiology	Yes
Gregory Roberts, MD, FACC	Internal Medicine Cardiovascular Disease	Nuclear Cardiology	**No**
Michael Romig, DO, FACC	Cardiology Echocardiography	Internal Medicine Nuclear Cardiology	Yes
Carin Smith, MD, FACC	Internal Medicine Cardiovascular Disease Echocardiography	Cardiovascular CT Nuclear Cardiology	Yes

Source: Wilmington Health website, https://www.wilmingtonhealth.com/find-adoctor/cardiology (visited 9/15/23).

Wilmington Health has only one board certified interventional cardiologist, Dr. Andrew Bishop. Dr. Bishop is the only Wilmington Health cardiologist who performs therapeutic cardiac cath procedures. He also has the highest volume of diagnostic cath lab procedures of the Wilmington Health cardiologists. The table below shows Dr. Bishop accounted for 47% of all Wilmington Health physicians' diagnostic cath lab procedures in NHNHRMC's cath labs in 2020. Dr. Bishop has consistently performed the highest number of diagnostic cath lab procedures and is the sole Wilmington Health provider who can perform interventional cath lab procedures.

Wilmington Health Physicians' Diagnostic Cath Lab Patients at NHNHRMC, 2018-2020

Physician	2018	2019	2020
Bishop, Andrew H.	362	476	385
Janik, Matthew J.	216	311	273
Payne, Paul A.	225	100	0
Roberts, Gregory J.	98	128	111
Romig, Michael C.	0	0	22
Smith, Carin J.	0	0	28
Total Wilmington Health cardiologists	**901**	**1,015**	**819**
% of Dr. Bishop's patients as % of total Wilmington Health cath patients	40%	47%	47%
Total other cardiologists not associated with Wilmington Health	**3,956**	**4,221**	**3,812**
Total all cardiologists	4,857	5,236	4,631

Source: Novant Health Internal Data

Dr. Bishop's involvement in this project is key to WASC meeting its volume projections and to its ability to serve area patients in need of both diagnostic and interventional cath lab procedures. Dr. Bishop did not submit a letter of support for either WASC's 2021 or 2023 applications. He has not stated what percentage of his volume he would shift to WASC. Even in the highest volume year, 2019, without Dr. Bishop's volume, the remaining Wilmington Health physicians performed only 539 diagnostic procedures, fewer than are projected in all three full project years (668, 676 and 685). Dr. Bishop's participation is critical to the WASC project yet there is no evidence that he will in fact participate. Given the criticality of Dr. Bishop's participation, it was incumbent upon the applicant to make an affirmative showing that Dr. Bishop will participate, but it failed to do so in two reviews, two years apart.

Access for Patients with Limited Financial Resources

WASC has not shown its project will be accessible to patients with limited financial resources. WASC failed to provide a percentage of charity care patients in Section L of its application, stating that Wilmington Health's "internal data does not include Charity Care as a payor source for patients."[9] This is also the case for NH. However, it must be possible for Wilmington Health to identify patients to whom charity care is provided. Otherwise, WASC would have no basis for calculating "the number of charity care patients at WASC who receive care at no cost as a percentage of total patients served", which WASC used to project the total number of charity care patients at the ASC.[10] WASC estimates 43 WASC patients will receive procedures at no or reduced cost, across the entire ASC patient volume. This equates to 0.74% of Wilmington ASC's 5,800 ASC patients in project year three. As the 43 includes surgical and cath lab patients, it is unclear how many cath lab patients would receive free or reduced price care.

The WASC financial assistance policy, included as Exhibit B.20-5, makes no commitment to provide free care. It does not explain the criteria to qualify for charity care, other than stating charity care is "available for patients who meet charitable guidelines as determined by the U.S. Department of Health & Human Services Annual Poverty Guidelines." These U.S. Department of Health & Human Services' Annual Poverty Guidelines provide information on income level and household size to determine whether someone is living in poverty, as the Department defines it. These guidelines provide no guidance on what level of income qualifies for free or reduced cost healthcare at WASC. The Guidelines do not commit WASC to offer charity care or specify amounts of charity care. WASC does not state what percent of the Poverty Guidelines' household income qualifies for charity care. The WASC policy also does not provide detail on how much the required payment will be reduced for patients who qualify for Financial Assistance. The WASC policy states that if a patient qualifies "a Financial Hardship Adjustment will be made on the patient's account for the approved percentage" but makes no indication of what percentage or range of percentages that might be.

In contrast, NH's charity care, included in Exhibit L-4.1, clearly defines that to be eligible for charity care (free care), a patient must be uninsured and have annual family income less than or equal to 300% of the Federal Poverty guidelines to receive charity care. Eligible patients may fill out a form and, if deemed

[9] WASC CON application, p. 102.
[10] WASC CON application, p. 106.

eligible, receive their care at no cost. This policy applies to all emergency and medically necessary care, which includes cath lab services.

While WASC provides assurances it will serve Medicaid patients at no cost for the first three full project years, it has provided no evidence that Medicaid patients will have reasonable access to WASC's cath lab in the long-term. WASC states that "North Carolina Medicaid does not reimburse for cardiac catheterizations performed in an ASF" but that it "believes that the North Carolina Medicaid Managed Care program will reimburse for cardiac catheterizations performed in an ASF in the near future."[11] It gave no support for this speculative statement. WASC made no commitment to continue serving Medicaid patients after three years if North Carolina Medicaid does not pay ASCs for cath lab procedures.

For all these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (1).

Criterion (3)

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

Wilmington ASC's Utilization Assumptions are not Reasonable or Adequately Supported

WASC's volume projections rely heavily on Dr. Bishop's historical volume, as he is the only interventionalist on staff and has the highest volume of cath lab procedures among Wilmington Health's cardiologists. Without support from Dr. Bishop, WASC has not adequately supported its projected cath lab volumes. In addition, Exhibit I.2 to WASC's CON application included a letter of support from a nurse practitioner, Steve Snyder, who cannot perform cath lab procedures. The Agency should not view that letters as support from a provider who is able to contribute to the cath lab volume, even though the letter mistakenly includes language about his opinion "as a physician."[12]

WASC did not adequately support the percentage of cath lab procedures it assumes its physicians will shift to WASC. Wilmington ASC limits its projected volume to the "WH Performed" cardiac catheterization procedures for the CPT codes now approved by CMS to be performed in an ASC.[13] On page four of its Form C Methodology and Assumptions, Wilmington ASC states that "at a minimum, 52.6 percent of diagnostic cardiac catheterizations and 40.5 percent of interventional cardiac catheterizations *could* be performed at

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[11] WASC CON Application, p. 107.

[12] *See* WASC Exhibit I.2 letters from Steve Snyder, MSN, FNP, Jake Farnsworth, DNP, Stephanie Collins, PA-C, Carrie A. Emory, PA-C, Craig Webb, PA-C

[13] Wilmington ASC CON Application, Form C Utilization—Methodology and Assumptions, pp.2-3. See Table 2.

Wilmington ASC, and therefore Wilmington ASC *could* treat that volume."[14] 52.6 percent and 40.5 percent are the percent of diagnostic and interventional procedures in the CMS approved CPT list for ASCs that Wilmington Health physicians performed on outpatients in CY 2020, respectively. They performed these procedures in a hospital outpatient department (HOPD); specifically, at NHNHRMC. However, not all patients who received a procedure that CMS *allows* to be performed at an ASC were *suitable* to have the procedure at an ASC due to the patient's characteristics. The Agency should not assume that simply because a procedure *could* be performed in an ASC means it *will* be performed in an ASC.

The Society for Cardiovascular Angiography and Interventions (SCAI) is "the only professional medical society in the US dedicated solely to interventional cardiology."[15] It published the most recent "SCAI Expert Consensus Statement on Percutaneous Coronary Intervention without On-Site Surgical Backup" in January 2023.[16] The publication was publicly available to WASC when WASC filed its application. In the 2023 publication, SCAI concludes that "adequate operator experience, appropriate clinical judgment and case selection, and facility preparation are essential to a safe and successful PCI program with no" on-site open heart surgery.[17] On patient selection, SCAI states:

> *As noted previously judicious case selection is paramount for the safe performance of AMB-PCI. Most patients with acute coronary syndromes are admitted to the hospitals and therefore are not considered for procedures in ASCs/OBLs. Patient comorbidities, particularly those that might require ancillary support, would favor the hospital setting:*
>
> 1. *Decompensated heart failure/severe left ventricular dysfunction*
> 2. *Respiratory compromise (hypoxia at rest)*
> 3. *High risk of blood transfusion*
> 4. *At risk for acute kidney injury*
> 5. *History of severe contrast allergy*
> 6. *Critical valvular heart disease*
> 7. *Any condition likely to require overnight observation*
>
> *Other scenarios not listed here may also favor the hospital setting; the guiding principle for the physician should be to avoid cases with a significant possibility of requiring support beyond what can be readily provided in the ambulatory setting.*

Wilmington ASC did not limit its projected volume to those outpatient procedures and patients that were clinically appropriate for an ASC-based cath lab. Instead, Wilmington ASC arbitrarily and with no support assumed "90 percent of all current 'WH Performed' cardiac catheterization procedures will shift to Wilmington ASC's unit of cardiac catheterization equipment."[18] Wilmington ASC provides no evidence this is a reasonable assumption.

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[14] *Ibid.*, p. 4.

[15] Society for Cardiovascular Angiography & Interventions. https://scai.org/

[16] Grines, Cindy et al. SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup. *JSCAI 2 (2023)*

[17] Grines, Cindy. Op Cit., p.

[18] Wilmington ASC CON application, Form C Utilization – Methodology and Assumptions, p. 7.

The SCAI paper calls into question the assumption that 90 percent of all Wilmington Health physicians' outpatients who had procedures CMS allows at an ASC would be clinically appropriate to receive their care at an ASC. The 2023 SCAI paper states:

> *At present, only 0.9% of 2021 Medicare claims for coronary stenting Current Procedural Terminology (CPT) code 92928 occurred in ASCs, with the remaining 99% split evenly between inpatient and outpatient hospital procedures.[19] In a commercial insurance claims database, 0.9% of ambulatory PCIs from 2007 to 2016 were done in ASCs and 99.1% were done in hospital outpatient departments.[20] However, the Bain & Company Medtech Physician survey estimates that up to 33% of all cardiac procedures will move to the ambulatory setting in the coming years.[21]*

PCIs, or percutaneous coronary interventions, are interventional cardiac catheterization procedures. In SCAI's discussion of these procedures, the highest historical percent of procedures performed in ASCs was less than one percent. While NH understands the percentage of PCIs performed at an ASC will increase, Wilmington ASC provides no evidence or reasonable explanation why they expect 90 percent of their historically performed outpatient procedures to be performed at an ASC.

Wilmington ASC also states: "If approved, WASC will be the only freestanding provider of cardiac catheterization services in the service area, and therefore the **primary provider** of outpatient cardiac catheterization care."[22] (emphasis added). It is unreasonable to suggest the *majority* of outpatient cath lab procedures will shift to Wilmington ASC on approval. It is unreasonable to assume that with one cath lab open only on weekdays[23] and with only one provider able to perform interventional procedures the proposed project will provide the largest number of outpatient cath procedures.

As discussed under Criterion (1), WASC did not include sufficient staffing for the projected patient volume. The Agency does not have reasonable assurance WASC can deliver the services described in the WASC application with the staffing described in the application.

For all these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (3).

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[19] American Medical Association Relative Value Update database. Physician Payment Policy and Systems, American Medical Association, Chicago, IL Accessed July 31, 2022. https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id¼prod280002&navAction¼push.
[20] Li K, Kalwani NM, Heidenreich PA, Fearon WF. Elective percutaneous coronary intervention in ambulatory surgery centers. JACC Cardiovasc Interv. 2021;14(3): 292–300.
[21] van Biesen T, Johnson T, Bain & Company. Ambulatory surgery center growth accelerates: is Medtech ready? Accessed April 18, 2022. https://www.bain.com/insights/ambulatory-surgery-center-growth-accelerates-is-medtech-ready/
[22] Wilmington ASC CON Application, Form C Utilization –Methodology and Assumptions, p. 3.
[23] Wilmington 2023 License Renewal Application.

WASC Has Not Reasonably Shown it Will Meet the Performance Standard

The relevant performance standard for fixed cardiac catheterization equipment is outlined in 10A NCAC 14C.1603(a).

> *a) An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
> *(1) identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*
> *(2) identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*
> *(3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*
> *(4) provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*
> *(5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*

The Agency should find WASC non-conforming with this performance standard because it did not adequately show the need for the proposed projects or that its assumptions, data, and methods support the projected volume. Please see the discussion under Criterion (3). WASC did not budget adequate staffing to safely support the volume it projects. Please see the discussion under Criterion (1).

WASC Did Not Show Access for Low Income Patients

WASC failed to provide a percentage of charity care patients in Section L of its application, stating that Wilmington Health's "internal data does not include Charity Care as a payor source for patients."[24] This is also the case for NH. However, it must be possible for Wilmington Health to identify patients to whom charity care is provided. Otherwise, WASC would have no basis for calculating "the number of charity care patients at WASC who receive care at no cost as a percentage of total patients served", which WASC used to project the total number of charity care patients at the ASC.[25] WASC estimates 43 WASC patients will receive procedures at no or reduced cost, across the entire ASC patient volume. This equates to 0.74% of

[24] WASC CON application, p. 102.
[25] WASC CON application, p. 106.

Wilmington ASC's 5,800 ASC patients in project year three. As the 43 includes surgical and cath lab patients, it is unclear how many cath lab patients would receive free or reduced price care.

The WASC financial assistance policy, included as Exhibit B.20-5, makes no commitment to provide free care. It does not explain the criteria to qualify for charity care, other than stating charity care is "available for patients who meet charitable guidelines as determined by the U.S. Department of Health & Human Services Annual Poverty Guidelines." These U.S. Department of Health & Human Services' Annual Poverty Guidelines provide information on income level and household size to determine whether someone is living in poverty, as the Department defines it. These guidelines provide no guidance on what level of income qualifies for free or reduced cost healthcare at WASC. The Guidelines do not commit WASC to offer charity care or specify amounts of charity care. WASC does not state what percent of the Poverty Guidelines' household income qualifies for charity care. The WASC policy also does not provide detail on how much the required payment will be reduced for patients who qualify for Financial Assistance. The WASC policy states that if a patient qualifies "a Financial Hardship Adjustment will be made on the patient's account for the approved percentage" but makes no indication of what percentage or range of percentages that might be.

In contrast, NH's charity care, included in Exhibit L-4.1 clearly defines that to be eligible for charity care (free care), a patient must be uninsured and have annual family income less than or equal to 300% of the Federal Poverty guidelines to receive charity care. Eligible patients may fill out a form and, if deemed eligible, receive their care at no cost. This policy applies to all emergency and medically necessary care, which includes cath lab services.

For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (3).

WASC Erroneously States a Potential NH Application is Inherently Non-Conforming with Criterion (3)

In 2022, NH submitted two petitions to adjust the need determinations in the *2023 SMFP* for cardiac catheterization equipment. The petitions called for no net need for cardiac cath equipment in New Hanover County, and a need for shared cardiac cath equipment in Brunswick County. The basis for the petitions was to ensure Brunswick County residents had access to both diagnostic and interventional cath lab services closer to their homes. Ultimately, the SHCC determined there was a need for cath lab equipment in both counties. Anyone was allowed to file applications to meet these need determinations, regardless of any positions taken in prior petitions.

After the need was published in the *2023 SMFP*, NH applied to meet the need determined by the State in New Hanover County for the reasons outlined in the CON application, and because NH is best able to meet area residents' needs. As a facility, NHNHRMC has the nursing staff, operational experts and clinical expertise to operate a safe, high-quality cath lab at its NH Scotts Hill campus. The NH medical staff has the experienced cardiologists, both independent physicians and employed physicians, to perform the full range of inpaient and outpatient cardiac proceures and to meet the performance standard for all laboratories.

The WASC CON application discusses NH's 2022 petitions. The first part of the discussion, quoted below, addresses NH's comments on the need for additional cardiac cath services in Brunswick County and New Hanover's existing capacity for cardiac catheterization.

> Interestingly, despite the lack of cardiac catheterization units in nearby counties, and despite NHNHRMC's own high volume, it should be noted that, in July 2022, Novant submitted a petition to remove the need determination for one fixed unit of cardiac catheterization equipment in New Hanover County in the *2023 SMFP*, while simultaneously submitting a complementary petition to add a need determination for one shared fixed unit of cardiac catheterization equipment in Brunswick County, noting, that "a need for additional cardiac catheterization services in southeastern North Carolina…exists in Brunswick County, not New Hanover County" and that "New Hanover County has sufficient cardiac catheterization resources for the foreseeable future."[22] While the Agency approved Novant's petition for an adjusted need determination in Brunswick County, the Agency denied Novant's petition to remove the need determination for one fixed unit of cardiac catheterization equipment in New Hanover County, citing the fact that New Hanover County has experienced a strong upward trend in cardiac catheterization utilization, which in turn generated the need determination in the *2023 SMFP*.[23] Given that NHNHRMC is the only provider of cardiac catheterization services in New Hanover County, this implicitly indicates that NHNHRMC therefore has experienced a strong upward trend in cardiac catheterization utilization.

Wilmington Health filed Comments in Opposition to NH's petition for an adjusted need determination in New Hanover County, stating 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."[26] In its current application, NH conducted an analysis to assess what percentage of Brunswick and Columbus County residents could reasonably be expected to use cath lab services at NHBMC. The results are discussed in the Assumptions and Methodology text after Form C.2b of NH's CON application. NH reviewed CY2022 data for all Brunswick and Columbus County inpatients discharged from NHNHRMC or NHBMC for the Diagnosis Related Groups (DRGs) for which both hospitals had twelve or more discharges in CY2022. NH calculated the percentages of Brunswick and Columbus County patients who received care at NHNHRMC and the percentages who received care at NHBMC. The table below shows the percentages.

Patient Destination for DRGs for which Both Hospitals 12 or More Discharges

	NHNHRMC	**NHBMC**
Brunswick County residents	47%	53%
Columbus County residents	81%	19%

Source: Novant Health Internal Data, CY2022

Based on these percentages, NH projected that 53 percent of clinically appropriate patients in need of cath lab services living in Brunswick County would choose to receive care at NHBMC while 47 percent would choose to receive care at NHNHRMC. Based on this analysis, NHNHRMC determined an additional cath lab was needed on the NHNHRMC license, even assuming approval of a cath lab at NHBMC. Simply stated: with further analysis of more recent data, NH concluded there will be sufficient cath lab volume to

[26] Wilmington Health. 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

support a seventh fixed cath lab on the NHNHRMC license and a shared cath lab at NHBMC. This is shown in Section C of NH's CON application and in the text that follow Form C.2b in Section Q.

In its application, WASC next argues that Novant Health's petition renders "any future certificate of need it might file for that need determination inherently nonconforming with Criterion 3."[27] WASC cites the Agency's decision in the 2022 Durham/Caswell Acute Care Bed Review as support for its statement. The full discussion is quoted below.

> There is precedent for an applicant's previous petitions regarding a need determination factoring into the ultimate decision regarding that need. For example, in its 2022 Durham/Caswell Acute Care Bed Review, the Agency found the application submitted by Duke University Hospital non-conforming with Criterion 3, noting that it was applying for a need determination for acute care beds in the given service area *despite* submitting a summer petition in July 2021, in which Duke University Hospital proposed, amongst other propositions, "that the need determination for 67[24] inpatient acute care beds in Durham and Caswell Counties in Chapter 5 be eliminated."[25] The Agency, in its findings, further stated that:
>
> > *...[L]ess than a year after Duke submitted the petition to the SHCC, before all of its approved beds were brought online and in use, and despite its stated need to eliminate or defer the*
> >
> > *2022 need determination for acute care beds, Duke filed this application to develop 68 new acute care beds...Duke did not explain in its application as submitted what circumstances changed between July 2021...and when Duke submitted the current application.[26]*
>
> WASC believes that, if Novant *were* to apply for one unit of cardiac catheterization equipment in New Hanover County pursuant to the need determination in the *2023 SMFP*, the Agency's finding of non-conformity as cited above would remain relevant, given that Novant specifically noted that New Hanover County has "sufficient cardiac catheterization capacity" regarding the current need determinations, making any future certificate of need it might file for that need determination inherently non-conforming with Criterion 3. WASC does not, however, challenge the SHCC's approval of Novant's petition to add an adjusted need determination of one fixed shared unit of cardiac catheterization equipment to Brunswick County in the *2023 SMFP*; the needs of both communities can certainly exist in tandem. Further, while circumstances may change from the filing of a petition to remove the need and the need determination that is nonetheless available for review, WASC is aware of no changes in New Hanover County that would reasonably allow Novant to change its position regarding the lack of need in the county.

WASC omitted part of the Agency's findings from its quotation. The Agency stated on page 13 of its findings: "Further, Duke provided no response to comments submitted during the public comment period that pointed out the discrepancy in Duke's position."[28] By omitting this sentence and only quoting the sentence on what was included in Duke's application, WASC mischaracterized the grounds upon which the Agency found Duke nonconforming.

NH's petitions assumed all Brunswick County residents who received cath lab services at NHNHRMC would eventually[29] receive cath lab services at NHBMC, if NH was approved to add a cath lab there. The new analysis in NH's CON application of the likely destination pattern for Brunswick and Columbus County residents is the changed circumstance that shows the SHCC was correct to find more cath lab capacity is needed in both New Hanover *and* Brunswick counties. This new analysis differentiates the NH CON

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[27] WASC CON application, page 49.

[28] 2022 Durham/Caswell Acute Care Bed Review. Project ID#s J-12211-22 and J-12214-22, page 13.

[29] The "# Cases in Brunswick County" line on page three of the Petition to the State Health Coordinating Council Adjustment to Need Determination for Cardiac Catheterization for New Hanover County 2023 State Medical Facilities Plan reflects a ramp up to this.

application from the Duke CON application. NH also forthrightly addressed the issue of patient choice and destination in its application.

Criterion (4)

(4)	**Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.**

An applicant whose volume projections are not reasonable and adequately supported does not propose the least costly or most effective alternative. As discussed under Criterion (3), WASC's volume projections depend on unsupported assumptions. In addition, the proposed WASC cath lab will be used only by a limited range of patients, specifically, low-risk, non-emergent outpatients who need scheduled outpatient cath services, and will receive one of the thirteen CPT code procedures listed in WASC's Exhibit C-4.5.

For all these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (4).

Criterion (5)

(5)	**Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.**

WASC's cath lab volume projection is not reasonable, reliable, and adequately supported. The projection relies on several unreasonable assumptions, including a 90 percent shift of Wilmington Health physicians' cath lab patients who received a CMS-approved CPT procedure, and reliance upon only one interventionalist, who did not express support for the application. Please see the discussion under Criterion (3) and Criterion (1). Without reasonable, reliable, and adequately supported volume projections, all projections of operating revenues and expenses are also unreliable.

As discussed under Criterion (1), WASC does not include sufficient staffing in its proposal to operate a safe, high-quality cath lab with seven pre and post-procedure bays. That discussion is incorporated here by reference. WASC's minimal staffing plan raises concerns about patient safety and also raises the obvious question whether WASC intentionally understated the staffing costs to make WASC appear a less expensive alternative than NH. The financial projections in Form H and Form F.3b do not reflect the full costs associated with staffing a cath lab. By omitting necessary staffing costs, WASC did not show the financial feasibility of the proposal.

WASC also did not show the availability of funds for development and start-up. The WASC application included no start-up costs, stating that as a "currently operational ASF" the cath lab project "will not result

in any start-up or operating expenses."[30] This is wrong. Nowhere in the previously approved ASF CON application (Project I.D. No. O-11441-17) did WASC say it will hire a registered radiologist technician, a registered cardiovascular invasive specialist, a registered nurse, and an LPN to work in a future cardiac catheterization lab. None of these employees will be on staff when the proposed project becomes operational, making the staff hiring and training a start-up expense. WASC did not properly account for the start-up costs of this project, and has not identified a source to fund these.

For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (5).

Criterion (6)

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

WASC fails to adequately demonstrate the need for its proposed project. See the discussion under Criterion (3), incorporated herein. Therefore, WASC did not adequately show its project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. See Criterion (3), which is incorporated herein by reference. For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (6).

Criterion (7)

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

Wilmington Health has only one interventional cardiologist, Dr. Andrew Bishop. One hundred percent of Wilmington Health's interventional cath lab procedures are performed by Dr. Bishop. If Dr. Bishop goes on vacation or is out sick, there is no interventionalist available to perform procedures in the WASC cath lab. Compared to his colleagues, Dr. Bishop also treats the largest number of Wilmington Health's diagnostic cath lab patients (47% in 2020). Any changes in Dr. Bishop's availability would greatly reduce WASC's ability to provide cath lab services to area residents. In evaluating the availability of an interventional cardiologist for WASC's proposed project, the Agency should also note that WASC did not state its ASC would be available to providers not employed by Wilmington Health.

As discussed under Criterion (1), WASC's application did not include enough RN and LPN staffing for the proposed cath lab's pre and post-procedure monitoring area. That discussion is incorporated herein.

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[30] WASC CON Application, p. 82.

For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (7).

Criterion (13)

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

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

The WASC application does not meet the requirements of Criterion (13)(c). The payor mix tables show no amounts for charity care. See application, p. 102. Therefore, the Agency does not have sufficient information to determine that WASC will provide access to medically underserved groups such as medically indigent or low income persons.

The WASC financial assistance policy, included as Exhibit B.20-5, makes no commitment to provide free care. It does not explain the criteria to qualify for charity care, other than stating charity care is "available for patients who meet charitable guidelines as determined by the U.S. Department of Health & Human Services Annual Poverty Guidelines." These U.S. Department of Health & Human Services' Annual Poverty Guidelines provide information on income level and household size to determine whether someone is living in poverty, as the Department defines it. These guidelines provide no guidance on what level of income qualifies for free or reduced cost healthcare at WASC. The Guidelines do not commit WASC to offer charity care or specify amounts of charity care. WASC does not state what percent of the Poverty Guidelines' household income qualifies for charity care. The WASC policy also does not provide detail on how much the required payment will be reduced for patients who qualify for Financial Assistance. The WASC policy states that if a patient qualifies "a Financial Hardship Adjustment will be made on the patient's account for the approved percentage" but makes no indication of what percentage or range of percentages that might be.

In contrast, NH's charity care, included in Exhibit L-4.1 clearly defines that to be eligible for charity care (free care), a patient must be uninsured and have annual family income less than or equal to 300% of the Federal Poverty guidelines to receive charity care. Eligible patients may fill out a form and, if deemed

eligible, receive their care at no cost. This policy applies to all emergency and medically necessary care, which includes cath lab services.

For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (13).

Criterion (18a)

(18a)	The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

WASC did not adequately show its proposal will have a positive impact upon the cost effectiveness, access and quality of the proposed services. These deficiencies were discussed in these comments under Criteria (1), (3), (4), (5), (6), (7) and (13) and are incorporated herein. WASC has not shown it has sufficient physician or nursing staff to provide the array of services it includes in its application, or to safely staff the seven-bay pre- and post-procedure area. The WASC project will not enhance cost effectiveness, quality or access for most area patients.

For these reasons, and any others the Agency may determine, the WASC application should be found non-conforming with Criterion (18a).

Comparative Review (1 = more effective)

Comparative Factor	NH Scotts Hill	Wilmington ASC
Conformity with Statutory and Regulatory Review Criteria	Yes	No
Scope of Services	1	2
Historical Utilization	1	2
Geographic Accessibility (Location within Service Area)	1	2
Access by Service Area Residents	1	2
Access Underserved Groups- Charity Care	Inconclusive	
Access Underserved Groups- Medicare	Inconclusive	
Access Underserved Groups- Medicaid	1	2
Competition (Access to a New or Alternative Provider)	1	2
Projected Average Net Revenue per Patient, Procedure, Case or Visit	inconclusive	
Projected Average Total Operating Cost per Patient, Procedure, Case or Visit	inconclusive	
Lower Cost Outpatient Cardiac Cath Services	2	1
Total Rank	1	2
Number of Factors Won	6	1

Conformity with Review Criteria

To be comparatively superior, an application much conform to all statutory review criteria. The WASC application is non-conforming with Criteria (1), (3), (4), (5), (6), (7), (13), (18a) and Policy GEN-3 and is non-conforming with the performance standard. The NH application is conforming with all applicable review criteria and the performance standard. As for this comparative factor, NH Scotts Hill's application is the more effective alternative.

Scope of Services

Generally, the more effective alternative regarding this comparative factor is the application offering the greater scope of services. Both applications propose to acquire a fixed cardiac cath lab but WASC is an ASC limited to only 13 procedures/CPT codes for a limited set of scheduled patients. It will not treat inpatients or emergency patients. The applicant's representation that it will provide interventional procedures is questionable because Wilmington Health's only interventionalist, Dr. Bishop, did not provide a letter of support for the project so there is no way to know whether he intends to use the WASC cath lab. The NH Scotts Hill cath lab will be in an acute care general hospital providing both emergency, inpatient, and outpatient services. Because it has hospital capabilities, and a larger medical staff of experienced interventionalists, it can provide a wider array of procedures to a wider array of area residents. Exhibit L-3 of the NH application lists 21 CPT codes and 31 ICD-10 codes NH intends to perform at the NH Scotts Hill cath lab. This list was developed by NH's HVI team, including Dr. Frederick Meine. Expressed as a percentage, WASC projects performing only 20 percent of the outpatient interventional

procedures NH Scotts Hill will perform. Therefore, NH Scotts Hill is the more effective alternative in regards to Scope of Services.

Historical Utilization

The table below shows CY 2022 reported volume of the applicants from the Proposed 2024 SMFP.

CY 2022 Cath Lab Volume

	Diagnostic Cases	Interventional Cases	Weighted Equivalents
NHNHRMC	3,029	2,371	7,178.25
WASC	0	0	0

Source: 2024 SMFP, p 311

The Agency generally favors an applicant with higher historical volume, based on the assumption that the provider has a greater need for the fixed units to serve its projected patients.[31] Although NH Scotts Hill will be a new hospital campus with no historical cardiac cath volume, it will be under the NHNHRMC license. NHNHRMC has five existing and one CON-approved but not yet operational cardiac cath labs. NH Scotts Hill will offer current NH patients greater access to cardiac cath services in New Hanover County. WASC does not currently operate any cardiac cath machines and is not affiliated with any cardiac cath labs in New Hanover County. Therefore, NH Scotts Hill is the more effective alternative regarding this factor.

Geographic Accessibility (Location within Service Area):

WASC is located across 17th Street (less than one mile) from the NHNHRMC Main Campus. NH Scotts Hill will be located over 18 miles from these facilities, on the other side of New Hanover County. Its distance from existing cardiac cath laboratories makes NH Scotts Hill a new site of care for service area residents. Therefore, for this comparative factor, the NH Scotts Hill application is the more effective alternative.

Access by Service Area Residents

Generally, the application projecting to serve the highest number of service area residents per each of unit of fixed cardiac cath equipment is regarded as the more effective alternative for this comparative review factor. However, both applicants are applying for one cardiac cath machine, so this measurement is not useful. A more useful way to evaluate access by service area residents is to compare the number and percent of total New Hanover patients projected in Project Year 3. The table below shows NH Scotts Hill projects more patients from New Hanover County than WASC. The table also shows that NH Scotts Hill projects a larger percentage of New Hanover County patients than WASC.

[31] 2021 New Hanover County Cardiac Cath Review Findings, p 54

Applicant	Projected New Hanover County Cath Lab Patients Served in Year 3	New Hanover County Residents Served as a Percent of Total	# of units of Fixed Cardiac Cath Equipment	New Hanover County Residents per Cardiac Cath Equipment
NH Scotts Hill	350	46.0%	1	350
WASC	347	41.2%	1	347

Source: CON Applications, Section C, Question 3 and Section A, Question 5.f.

Therefore, for this comparative factor, NH Scotts Hill's application is the more effective alternative.

Access by Underserved Groups- Charity Care

WASC did not include a number or percentage of charity care patients for cath lab services. Without that information, the best proxy is charity care deduction as a percent of total net revenue in Project Year 3. In past findings, the Agency has also considered the charity care deduction per projected cardiac cath procedure as a measure for this comparative review factor. The table below compares the applicants projected charity care as a percentage of total net revenue. It also shows charity care dollars for cath lab services per projected cardiac cath procedures in Project Year 3.

Applicant	Charity Care Deduction from Revenue Year 3	Cardiac Cath Procedures	Charity Care Deduction from Revenue as a Percent of Total Net Revenue Year 3	Charity Care/Cardiac Cath Procedure
NH Scotts Hill	$739,726	763	10%	$969
WASC	$119,665	843	4%	$142

Source: Form F.2b

The table shows NH Scotts Hill projected more charity care dollars for cath lab procedures in Project Year 3 than WASC. Not only does NH Scotts Hill expect to spend more on charity care, but its projected charity care deduction as a percent of total net revenue is more than double WASC's. NH Scotts Hill also projects spending more on charity care per cardiac cath procedure than WASC. Therefore, NH Scotts Hill is the more effective alternative regarding this comparative review factor.

In the 2021 New Hanover County Cardiac Cath Findings, the Agency found the analysis for this comparative review factor inconclusive stating, "…differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants may impact the averages …"[32] These differences exist in the applicants for this comparative review; therefore, this factor is inconclusive.

[32] 2021 New Hanover County Cardiac Cath Review Findings, p 57

Access by Underserved Groups-Medicare

The following table compares the number of Medicare patients in Project Year 3 and Medicare patients as a percentage of total patients. Generally, the application projecting the highest number or percentage is the most effective alternative regarding these comparative factors.

Applicant	Number of Medicare Patients	Percentage of Total Patients Served
NH Scotts Hill	492	64.4%
WASC	494*	58.6%

Source: Section L.3 and Form F.2b

WASC projects to serve two more Medicare patients than NH Scott Hill's projections for Project Year 3. Comparing just the number of Medicare patients, WASC is the more effective alternative.

However, there have been circumstance in the past where total number of Medicare patients was not available.[33] When this occurred, the Agency considered Medicare as a percent of gross revenue and Medicare gross revenue per cardiac cath procedure as metrics for this comparative review factor. The table below shows these metrics for each application's Project Year 3. Generally, the application projecting the highest number or percentage and/or the highest dollar amount of Medicare per cardiac cath procedure is the most effective alternative regarding these comparative factors.

Applicant	Medicare Gross Revenue	Cardiac Cath Procedures	Medicare Gross Revenue as Percentage of Total Gross Revenue	Medicare/Cardiac Cath Procedure
NH Scotts Hill	$24,463,807	763	64.4%	$32,063
WASC	$3,732,387	843	58.6%	$4,428

Source: Form F.2b, Form C.2b

NH Scotts Hill projects a higher percentage of Medicare gross revenue as percentage of total gross revenue than WASC. NH Scotts Hill also projects higher Medicare spending per cardiac cath procedure than WASC. Using these calculations, NH Scotts Hill is the more effective alternative regarding this comparative factor.

In the 2021 New Hanover County Cardiac Cath Findings, the Agency found the analysis for this comparative review factor inconclusive stating, "…differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants may impact the averages..."[34] These differences exist in the applicants for this comparative review; therefore, this factor is inconclusive.

[33] 2021 New Hanover County Cardiac Cath Review Findings

[34] 2021 New Hanover County Cardiac Cath Review Findings, p 57

Access by Underserved Groups Medicaid

The following table shows the number of Medicaid patients and Medicaid patients as a percentage of total patients in Project Year 3. Generally, the application projecting the highest number or percentage is the most effective alternative regarding these comparative factors.

Applicant	Number of Medicaid Patients	Percentage of Total Patients Served
NH Scotts Hill	20	2.6%
WASC	12	1.4%

Source: Section L Question 3.b. WASC application, p. 111. NH Scotts Hill App p. 98

NH Scotts Hill projects 40% more Medicaid patients in Project Year 3 than WASC. Medicaid patients as a percent of total patients is also higher at NH Scotts Hill than WASC.

In 2021, the Agency considered gross Medicaid dollars as a percentage of gross revenue for measuring this comparative review factor.[35] NH Scotts Hill includes $1,003,914 of Medicaid gross revenue in year three while WASC includes $90,036. Based on gross revenue, number of patients and percent of patients served, NH Scotts Hill is more favorable on this factor.

Competition

Generally, a new provider entering the service area is regarded as the most effective alternative by the Agency for this comparative review factor. Although NH Scotts will operate under the NHNHRMC license, it will be a new facility, at a new location, offering expanded access to New Hanover County residents.

The effectiveness of WASC as a competitor is limited. Because it can only provide non-emergency outpatient services to low-acuity patients, some patients may be excluded based on their specific condition. WASC can only treat Wilmington Health patients. NH Scotts Hill can treat all patients, regardless of their physician's medical group, and will provide a wider array of procedures. The NH cath lab will be available to all qualified physicians, including those employed by Wilmington Health. As discussed under Criterion (1) of these comments, WASC also does not include sufficient staffing in its proposal to operate a safe, high-quality cath lab with seven pre and post-procedure bays. That discussion is incorporated here by reference. As NH Scotts Hill's application shows, the NHNHRMC medical staff has more physicians, and a proven track record of providing quality care to its cardiac cath patients, which distinguishes NH Scotts Hill from WASC. WASC is the less effective alternative regarding this comparative factor.

Projected Average Net Revenue per Patient

The table below compares projected average net revenue per cardiac cath procedure for the third project year for both applications. Because a lower average net revenue may indicate lower cost to patient or

[35] 2021 New Hanover County Cardiac Cath Review Findings, p 58

third-party payor, the application proposing the lowest average net revenue per cardiac cath procedure is generally considered the more effective alternative.

Applicant	Total Cardiac Cath Procedures	Total Net Revenue	Average Net Revenue Per Visit
NH Scotts Hill	763	$ 7,470,485	$ 9,790.94
Wilmington ASC	843	$ 2,710,564	$ 3,215.38

Source: Form F2.b

The table shows that WASC projects lower average net revenue per cardiac cath procedure in the third year following project completion. However, results of this analysis are inconclusive because of differences in types of facilities (ASC v. HOPD) and NH Scotts Hill's broader range of procedures. (See 2021 Agency findings on Project ID #s O-12112-21 and O-12121-21, p. 60) Furthermore, WASC's minimal staffing plan mentioned in earlier parts of these comments raises concerns about patient safety and also raises the obvious question whether WASC intentionally understated the staffing costs to make WASC appear a less expensive alternative than NH. The financial projections in Form H and Form F.3b do not reflect the full costs associated with staffing a cath lab. By omitting necessary staffing costs, WASC appears to have painted an unrealistic picture of its financial feasibility.

Projected Average Total Operating Cost per Patient

The table below compares projected average operating expense per cardiac cath procedure for the third project year for both applications. Because a lower average operating expense may indicate lower cost to patient or third-party payor, the application proposing the lowest average operating expense per cardiac cath procedure is generally considered the more effective alternative.

Applicant	Total Cardiac Cath Procedures	Total Operating Costs	Average Operating Costs Per Visit
NH Scotts Hill	763	$ 4,283,754	$ 5,614.36
Wilmington ASC	843	$ 1,806,868	$ 2,143.38

Source: Form F2.b

The table shows that WASC projects lower average operating costs per cardiac cath procedure in the third year following project completion. However, results of this analysis are inconclusive because of differences in types of facilities (ASC v. HOPD) and NH Scotts Hill's broader range of procedures. (See 2021 Agency findings on Project ID #s O-12112-21 and O-12121-21, p. 60)

Furthermore, WASC's minimal staffing plan mentioned in earlier parts of these comments raises concerns about patient safety and also raises the obvious question whether WASC intentionally understated the staffing costs to make WASC appear a less expensive alternative than NH. The financial projections in Form H and Form F.3b do not reflect the full costs associated with staffing a cath lab. By omitting necessary staffing costs, WASC appears to have painted an unrealistic picture of its financial feasibility.

Lower Cost Outpatient Cardiac Cath Services

The 2021 New Hanover County Cardiac Cath Review stated for this comparative factor, "many, but not all, outpatient cardiac cath services can either be performed in a hospital licensed facility using fixed cardiac cath equipment or in an ASF using non-hospital licensed fixed cardiac cath equipment. However, the cost for that same service will often be much higher when the cardiac cath procedure is performed using hospital licensed fixed cardiac cath equipment or, conversely, much less expensive if performed using non-hospital licensed fixed cardiac cath equipment in an ASF.[36] Based on these findings, WASC is the more effective alternative for this comparative review factor.

Conclusion

WASC's application is non-conforming with many CON criteria and the performance standard and should not be approved. The NH Scotts Hill application is conforming to all criteria and performance standards and is also the more effective alternative on all but one comparative factors not deemed inconclusive. NH Scotts Hill is the superior application and should be approved while WASC should be denied.

[36] 2021 New Hanover County Cardiac Cath Review Findings, p 60

Exhibit 1

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Editorial

Percutaneous Coronary Intervention Without On-Site Surgical Backup—The Times They Are A-Changin'

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Many recognize the phrase attached to the title "The Times They Are A-Changin'" as the name of the 1964 record album by folk singer Bob Dylan.[1] That phrase seems like an appropriate way to describe the new phase of percutaneous coronary intervention (PCI) delivery in the United States and the reason for a new expert consensus statement on PCI without on-site surgical backup by the Society for Cardiovascular Angiography & Interventions (SCAI).[2] In my view, we are now moving into the third phase of PCI delivery in the US.

When PCI was first introduced in the US, it was restricted to hospitals with on-site surgery because up to 5.8% of patients needed urgent cardiac surgery for complications of the procedure.[3] Fibrinolytic therapy for acute myocardial infarction (MI) was also evolving, but over time, it was surpassed by PCI as the preferred way to achieve vessel patency.[4] Several transfer strategies combining fibrinolytic therapy and PCI emerged to provide reperfusion as fast as possible for patients in rural areas, but the success and appeal of primary PCI remained strong.[5]

The second phase of PCI delivery evolved because of a desire to provide primary PCI to all patients with acute MI. Accordingly, hospitals, many located in rural areas and performing only diagnostic cardiac catheterization, pushed to provide primary PCI services without on-site surgery. By limiting procedures at hospitals without on-site surgery only to patients with acute MI, it was difficult to maintain staff and operator proficiency, and it was financially unsustainable. The improving safety and success of PCI, aided by the development of stents and new antiplatelet and antithrombotic drugs, supported expansion of PCI into other patient groups and elective procedures at sites without on-site surgery. We are now starting the third phase of PCI delivery, with expansion to ambulatory surgery centers (ASCs) and office-based laboratories (OBLs); so, "The Times They Are A-Changin'" again.

Throughout the development of PCI and the expansion of PCI delivery, SCAI, in collaboration with other professional organizations, has provided guidance on the performance of PCI in these expanding settings; therefore, the new expert consensus statement on PCI without on-site surgical backup is timely.[2,6,7] The new expert consensus statement provides a comprehensive review of past and current PCI results for a variety of lesion types, demonstrating the continuing improvement in outcomes and safety of PCI in facilities with and without on-site cardiac surgery.[2] As PCI expands to ASCs and OBLs (together referred to as ambulatory PCI), the expert consensus statement provides standards for key structural elements, such as equipment, supplies, staffing, transfer agreements, operator requirements, case selection, and surgical consultation, in such facilities.[2] A straightforward algorithm intended for experienced operators (defined as 3-10 years of experience and the ability to independently practice all of interventional cardiology in any setting) has been provided to help operators determine the type of patients, type of lesions, and procedure locations for PCI.

It is important to emphasize that the expert consensus statement advises against ambulatory PCI for new operators, defined as <3 years' experience, with limited exposure to atherectomy devices, and for patients with ST-elevation MI or shock.[2] Some might think that this is too restrictive and point out that patients with ST-elevation MI or shock are not appropriate candidates for ambulatory PCI. Several years ago, one of the major manufactures of PCI balloons had as their slogan "because no angioplasty is ever simple." Many PCIs are straightforward until the guide catheter dissects and occludes the proximal right coronary artery; within 60 seconds, you are faced with a patient with hypotension and severe bradycardia. Even low-risk PCI can turn into a disaster, making one's prior experience invaluable in a setting such as ambulatory PCI, which may not be optimally staffed or equipped for the situation.

There is little question that ambulatory PCI provides a more convenient environment for both patients and physicians and can reduce costs. The cost savings makes this scenario very attractive to Medicare and other payers; however, moving forward to this third phase, what does this mean for the delivery of PCI and for patients and physicians? The move from the first phase, when PCI was only allowed at hospitals with on-site surgery, to the second phase, when PCI was allowed at hospitals without on-site surgery, occurred slowly and after multiple studies evaluating the safety and success of PCI without on-site surgery had been published. As shown in Table 1 of the expert

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consensus statement, studies examining the safety and outcomes of PCI at hospitals without on-site surgery continue to be published even though this scenario is now widely accepted both in the US and abroad.[2] This is in contrast to the body of evidence supporting the extension of PCI to ASCs and OBLs. As cited in the expert consensus statement,[2] <1% of PCIs have been performed in ASCs and OBLs, and only outcome data are unpublished. In 1 small study that used administrative data, PCIs performed in an ASC were significantly associated with higher bleeding complications and less likely to undergo functional testing of lesion severity.[8] Because PCIs performed in hospitals without on-site surgery have outcomes and complication rates equivalent to those performed in hospitals with on-site surgery, is it appropriate to make a leap of faith and extrapolate the same results to the new care setting, ambulatory PCI? Is this a bridge too far?[9] As defined in the expert consensus statement,[2] the care setting is clearly different; thus, in the absence of high-quality published data, questions about the safety and outcomes of ambulatory PCI remain unanswered.

No doubt, the cost savings for insurance providers will result in physicians being pressured to perform procedures in ASCs or OBLs. The same cost savings pressure was observed in the early days of same-day discharge, prompting SCAI to publish guidance for same-day discharge after PCI.[10] As emphasized in that document, physicians, not insurers, should determine whether same-day discharge is appropriate for a patient, and that same dictum applies to the new phase of PCI in ambulatory settings. Physicians should be the final authority in deciding which of the 3 patient care environments is appropriate for their patient; however, the ownership of this decision comes with the responsibility that physicians follow proper guidance and use good judgment in making this decision.

As we now enter this new phase of the delivery of ambulatory PCI, SCAI and its collaborating organizations have developed this expert consensus statement to provide needed guidance for physicians.[2] The expert consensus statement was founded upon a healthy dose of common sense and the substantial experience of the authors. The guidance set forth in the expert consensus statement provides a roadmap for all those currently involved with or contemplating involvement with PCI in ASCs and OBLs.[2] As Bob Dylan sang in 1964, “The Times They Are A-Changin’.”

Declaration of competing interest

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References

1. Dylan B. *The Times They Are A-Changin’*. Columbia Records; 1964.
2. Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on PCI without on-site surgical backup. Preprint. Posted online. *J Soc Cardiovasc Angiogr Interv*. doi:.
3. Detre KM, Holubkov R, Kelsey S, et al. Percutaneous transluminal coronary angioplasty in 1985–1986 and 1977–1981. *N Engl J Med*. 1988;318(5):265–270. https://doi.org/10.1056/NEJM198802043180501
4. Keeley EC, Boura JA, Grines CL. Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials. *Lancet*. 2003;361(9351):13–20. https://doi.org/10.1016/S0140-6736(03)12113-7
5. Cantor WJ, Fitchett D, Borgundvaag B, et al. Routine early angioplasty after fibrinolysis for acute myocardial infarction. *N Engl J Med*. 2009;360(26): 2705–2718. https://doi.org/10.1056/NEJMoa0808276
6. Dehmer GJ, Blankenship J, Wharton Jr TP, et al. The current status and future direction of percutaneous coronary intervention without on-site surgical backup: an expert consensus document from the Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv*. 2007;69(4):471–478. https://doi.org/10.1002/ccd.21097
7. Dehmer GJ, Blankenship JC, Cilingiroglu M, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. *J Am Coll Cardiol*. 2014;63(23):2624–2641. https://doi.org/10.1016/j.jacc.2014.03.002
8. Li K, Kalwani NM, Heidenreich PA, Fearon WF. Elective percutaneous coronary intervention in ambulatory surgery centers. *JACC Cardiovasc Interv*. 2021;14(3): 292–300. https://doi.org/10.1016/j.jcin.2020.10.015
9. Dehmer GJ. Elective percutaneous coronary intervention in ambulatory surgery centers: is this a bridge too far? *JACC Cardiovasc Interv*. 2021;14(3):301–303. https://doi.org/10.1016/j.jcin.2020.10.025
10. Chambers CE, Dehmer GJ, Cox DA, et al. Defining the length of stay following percutaneous coronary intervention: an expert consensus document from the Society for Cardiovascular Angiography and Interventions endorsed by the American College of Cardiology Foundation. *Catheter Cardiovasc Interv*. 2009; 73(7):847–858. https://doi.org/10.1002/ccd.22100

Exhibit 2

POSITION STATEMENT
for LPN Practice

A Position Statement does not carry the force and effect of law and rules but is adopted by the Board as a means of providing direction to licensees who seek to engage in safe nursing practice. Board Position Statements address issues of concern to the Board relevant to protection of the public and are reviewed regularly for relevance and accuracy to current practice, the Nursing Practice Act, and Board Administrative Code Rules.

INTRODUCTION

The Nursing Practice Act, G.S. 90-171.20(8) and North Carolina Administrative Code, 21 NCAC 36.0225 (LPN rules) govern Licensed Practical Nurse (LPN) practice in North Carolina. Reading this Position Statement and the LPN rules together serves to clarify the LPN Scope of Practice/Components of Practice for LPNs, RNs, employers, consumers, and others. Comparison with 21 NCAC 36.0224 (RN Rules) provides distinction from RN scope of practice.

LPN Scope of Practice in all steps of the nursing process is limited and focused because, by law, it is a dependent and directed scope of practice. LPN practice requires assignment or delegation by and performance under the supervision, orders, or directions of a registered nurse (RN), physician, dentist, or other person authorized by State law to provide the supervision. LPNs implement health care plans developed by the RN and/or by any person authorized by State law to prescribe such a plan.

Note: The practice of nursing is constantly evolving as new and changing technology and therapies are introduced. The North Carolina Board of Nursing defines and interprets scopes of practice for all levels of providers of nursing care. Each agency/employer is responsible for developing policies/procedures/standards of practice and ensuring competency of the nursing staff. An agency/employer, including a registered nurse or physician employer, may restrict the nurse's practice but never expand the practice beyond the legal scope as defined. LPN practice is not defined by specific activities or tasks, but rather as a process consisting of a set of legally defined Components of Practice using the steps of the nursing process as outlined in the LPN rules, 21 NCAC 36.0225.

For specific questions, the NCBON Scope of Practice Decision Tree for the RN and LPN is available at www.ncbon.com – select Nursing Practice on the top banner – select Position Statements and Decision Trees – select Scope of Practice Decision Tree. NCBON Practice Consultants can also be reached for clarification at 919-782-3211.

Critical Thinking: Critical thinking is used throughout all components of the nursing process. Critical thinking is purposeful and reflective judgment in response to events, observations, experiences, and verbal or written expressions. It involves determining the meaning and significance of what is observed or expressed to determine need for action. Nurses (RNs and LPNs) use critical thinking in clinical problem-solving and decision-making processes relative to scope of practice, knowledge, competency, and experience.

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Co-signature of LPN Documentation:
North Carolina nursing law and rules do not require LPN documentation to be co-signed by the RN. All nurses are responsible and accountable for their own actions and documentation. Agencies may, however, establish policies requiring RN co-signature of LPN documentation. Agency policy should define what the RN co-signature means. (For example, the co-signature might indicate "review", "agreement", or that every element has been checked by the RN depending upon the policy requirements.)

ACCEPTING AN ASSIGNMENT

The first decision required by the LPN is whether or not to accept the assignment given by the registered nurse, physician or other person authorized to make the assignment. The LPN shall accept only those assigned nursing activities and responsibilities, as defined in Paragraphs (b) through (j) of the LPN rules. Paragraph (a) of the LPN rules lists the variables in each practice setting which the LPN must consider in making this decision. Please see Position Statement, Accepting an Assignment, for additional guidance on this important topic at www.ncbon.com – select Nursing Practice on the top banner – select Position Statements – select Accepting an Assignment.

COMPONENTS OF LPN PRACTICE

ASSESSMENT, the first step of the nursing process and an essential component of nursing practice, is an ongoing process. Beginning with the initial encounter and continuing throughout the episode(s) of care, assessment is the basis for nursing judgments, decisions, and interventions. Nursing assessment is the gathering of information about a patient's physiological/biological, psychological, sociological, and spiritual status.

Both registered nurses and licensed practical nurses assess clients. Some elements of assessment are identical for both the RN and LPN. These include:

- The collection of data for a nursing history, psychological, spiritual, and social history, and physical examination (including vital signs, head to toe and/or targeted physical assessment, and other physiological/biological data);
- Comparison of the data collected to normal values and findings;
- Ongoing determination of client status for changes in condition, positive and negative.

For the LPN, nursing assessment is a focused appraisal of an individual's status and situation at hand, contributing to assessment, analysis, and development of a comprehensive plan of care by the RN. The LPN supports ongoing data collection and decides who to inform of the information and when to inform them. The LPN identifies the need for immediate assessment (beyond that specified in the plan of care) in response to current client status and condition. (National Council of State Boards of Nursing, Model Law and Rules, 2008)

The LPN participates in both initial and ongoing nursing assessments of the client's health status, including reaction to illness and treatment regimens while the RN retains overall responsibility for verifying data collected, interpreting data, and formulating nursing diagnoses.

"Participating in" means to have a part in or contribute to the elements of the nursing process.

Participation of the LPN in assessment is limited to:

- Collection of data according to structured written guidelines, policies and forms;
- Recognition of existing relationships between data gathered and the client's current health status;
- Determination of the need for immediate nursing interventions.

LPN Participation in "Initial", "Admission", or "Event-focused" Assessment:
These terms used by health care agencies to describe different types of assessments are not defined in nursing law and rules. The components of "initial", "admission", "event-focused" (e.g., post patient fall, pre-transfer, etc.), or other specifically-named assessment processes are defined by agency policy based on the laws and regulations, standards of care, accreditation standards, and reimbursement requirements applicable to specific practice settings. (For example, if federal Medicare regulations require that an RN perform the initial assessment, then the LPN cannot perform this assessment by proxy for the RN.) The LPN within scope of practice participates in any assessment process, if permitted by agency policy, using structured written guidelines, policies, and forms that outline the data to be obtained.

PLANNING is the second step of the nursing process. For the LPN, planning includes participation in the identification of the client's needs related to the findings of the nursing assessment. Elements of planning are listed in the LPN rules in Paragraph (c) and include:

- Identification of nursing interventions and goals for review by the RN;
- Participation in decision-making regarding the implementation of nursing and medical interventions utilizing assessment data;
- Participation in multidisciplinary planning by providing resource data

Therefore, the LPN provides important input in the planning process while the RN has the responsibility for developing the nursing plan of care and modifying the plan as indicated by ongoing assessment and evaluation.

IMPLEMENTATION is the third step of the nursing process and consists of delivering nursing care according to an established health care plan and as assigned by the RN or other person(s) authorized by law. Elements of implementation for the LPN are listed in the LPN rules in Paragraph (d)(1) and include the following:

- Procuring resources needed to implement the care plan;
- Implementing nursing interventions and medical orders consistent with nursing rules and within an environment conducive to client safety;
- Prioritizing performance of nursing interventions within assignment;
- Recognizing responses to nursing interventions;
- Modifying immediate nursing interventions based on changes in a client's status;
- Delegating specific nursing tasks as outlined in the plan of care and consistent with nursing rules.

The degree of supervision by an RN or other authorized person required for the performance of any assigned or delegated nursing activity by the LPN when implementing nursing care is determined by the variables listed in Paragraph (d)(3) of the LPN rules.

The LPN also participates in implementing the health care plan by assigning nursing care activities to other licensed practical nurses and delegating nursing care activities to unlicensed assistive personnel (UAP) qualified and competent to perform such activities providing certain essential criteria are met. These criteria are listed in the LPN rules in Paragraph (d)(2) and include:

- Assuring that competencies of personnel to whom nursing activities may be assigned or delegated have been validated by an RN;
- Continuous availability of a registered nurse for supervision;
- Participation by the LPN in on-going observations of clients and evaluation of client's responses to nursing actions;
- Accountability is maintained by the LPN for responsibilities accepted, including care provided by self and by all other personnel to whom care is assigned or delegated;
- Supervision provided by the LPN is limited to assuring that tasks have been performed as assigned or delegated and according to established standards of practice.

The appropriate and effective LPN delegation of nursing activities to UAP is an essential element in assuring safe client care. The NCBON Decision Tree for Delegation to UAP and the Position Statement on Delegation and Assignment of Nursing Activities (both available at www.ncbon.com) provide guidance for LPN practice.

It is beyond LPN scope of practice to assign nursing responsibilities to RNs.

Please note: Managing the Delivery of Nursing Care and Administering Nursing Services are not components within LPN Scope of Practice. Supervision by LPNs is limited to the assuring that tasks have been performed as assigned or delegated and according to established standards of practice as stated in Paragraph (d)(2)(E) of the LPN rules.

Therefore, it is beyond LPN scope of practice to be responsible for the following activities: nursing unit management, nursing administration, performance appraisal, orientation and teaching of nursing staff, validation of competence, or nursing staff development.

Please see Position Statements describing the limited role of the LPN in supervision within environments providing care for clients with relatively stable status (such as Skilled Nursing/Long Term Care Facilities) and the LPN role in staff development at www.ncbon.com – select Practice in left side column – select Position Statements – select:

- Nurse in Charge Assignment to LPN
- Staff Development

EVALUATION is the fourth step of the nursing process and consists of LPN participation in determining the extent to which desired outcomes of nursing care are met and in planning for subsequent care. Elements of evaluation by the LPN are listed in Paragraph (e) of the LPN rules and include:

- Collecting evaluative data from relevant sources according to written guidelines, policies, and forms;
- Recognizing the effectiveness of nursing interventions;
- Proposing modifications to the plan of care for review by the registered nurse or other person(s) authorized by law to prescribe such a plan.

REPORTING and RECORDING are those communications, written and verbal, required in providing the nursing care for which the LPN has been assigned responsibility. Reporting is the verbal communication of information to other persons responsible for or involved in the care of the client. Recording is the written or electronic documentation of information on the appropriate client record, nursing care plan or other documents. This documentation must reflect the verbal communication of information to other persons, and accurately describe the nursing care provided by the LPN. Both reporting and recording must be completed within a time period consistent with the client's need for care and according to agency policies and procedures. See LPN rules, Paragraph (f), for more information on the required elements of reporting and recording.

COLLABORATING involves communicating and working cooperatively in implementing the health care plan with individuals whose services may have a direct or indirect effect on the client's health care. As assigned by the RN or other person(s) authorized by law, the LPN participates in collaborating in client care. Elements of collaboration by the LPN are listed in the LPN rules in Paragraph (g) and include:

- Implementing nursing or multidisciplinary approaches for the client's care;
- Seeking and utilizing appropriate resources in the referral process;
- Safeguarding confidentiality.

TEACHING and COUNSELING of clients and their families may be implemented by the LPN utilizing an established teaching plan/protocol as assigned by the registered nurse, physician or other qualified professional licensed to practice in North Carolina. The LPN participates in teaching and counseling as listed in the LPN rules in Paragraph (h) by:

- Providing accurate and consistent information, demonstrations, and guidance to clients, their families or significant others regarding the client's health status and health care in order to
  - increase knowledge
  - assist the client to reach an optimum level of health functioning and participation in self care
  - promote the client's ability to make informed decisions;
- Collecting evaluative data and reporting this to the RN or other authorized person.

Teaching nursing activities to health care personnel is beyond the scope of practice of the LPN.

ACCEPTING RESPONSIBILITY for self for individual nursing action, competence and behavior is a component of practice shared by LPNs and RNs. The elements within this component of practice are listed in the LPN rules in Paragraph (j).

Please reference the LPN rules and the RN and LPN Scope of Practice Comparison Chart

References:

Nursing Practice Act, G.S. 90-171.20(8)
21 NCAC 36.0221 – License Required
21 NCAC 36.0224 – Rules for the Registered Nurse
21 NCAC 36. 0225 – Rules for the Licensed Practical Nurse
NCBON Decision Tree for Delegation to UAP
NCBON Position Statement - Delegation and Assignment of Nursing Activities
NCBON Scope of Practice Decision Tree for the RN and LPN
NCBON Position Statement – Nurse in Charge Assignment to LPN
NCBON Position Statement – Staff Development

NCBON Position Statement – RN and LPN Scope of Practice Comparison Chart

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Exhibit 3

PROCEDURAL SEDATION/ANALGESIA

NCBON
North Carolina Board of Nursing

POSITION STATEMENT
for RN Practice

A Position does not carry the force and effect of law and rules but is adopted by the Board as a means of providing direction to licensees who seek to engage in safe nursing practice. Board Position Statements address issues of concern to the Board relevant to protection of the public and are reviewed regularly for relevance and accuracy to current practice, the Nursing Practice Act, and Board Administrative Code Rules.

Issue: Administration of sedative, analgesic, and anesthetic pharmacological agents, for the purpose of Moderate or Deep Procedural Sedation/Analgesia, to non-intubated clients undergoing therapeutic, diagnostic, and surgical procedures, is within the non-anesthetist Registered Nurse (RN) scope of practice.

Administration of pharmacologic agents for Moderate and/or Deep Procedural Sedation/Analgesia by an RN (who is not a licensed/certified anesthesia provider) **requires all of the following**:

- Policies and procedures of employing agency authorize RN-administered Moderate and/or Deep Procedural Sedation/Analgesia;
- The RN possesses specific knowledge and validated competencies as described in this Position Statement;
- The RN responsible for sedation/analgesia administration and monitoring of a client receiving moderate or deep sedation/analgesia does NOT assume other responsibilities which would leave the client unattended, thereby jeopardizing the safety of the client;
- The physician, certified registered nurse anesthetist (CRNA), nurse practitioner (NP), or physician assistant (PA) ordering RN-administered Moderate Procedural Sedation/Analgesia is physically present in the procedure area and immediately available during the time moderate procedural sedation/analgesia is administered; and,
- The Physician, CRNA, NP, or PA ordering RN-administered Deep Procedural Sedation/Analgesia is physically present at the bedside throughout the time deep sedation/analgesia is administered.

The intended level of sedation/analgesia may quickly change to a deeper level due to the unique characteristics of the pharmacological agents used, as well as the physical status and drug sensitivities of the individual client. The administration of these pharmacologic agents requires ongoing assessment and monitoring of the client and the ability to respond immediately to deviations from the norm.

Given the level of independent assessment, decision-making, and evaluation required for safe care, nursing care of these clients exceeds Licensed Practical Nurse (LPN) scope of practice.

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Exclusions from NCBON Procedural Sedation/Analgesia Position Statement:

1. Advanced Practice Registered Nurse - Certified Registered Nurse Anesthetists (APRN-CRNAs) are professional anesthesia providers qualified by education, certification, licensure, registration, and experience to administer anesthesia and all levels of procedural sedation. CRNA scope of practice exceeds and is not limited by the constraints of this Position Statement.

   Administration of general anesthesia, including the use of inhalation anesthetics, is limited solely to anesthesia providers, including CRNAs. (Note: Nitrous oxide, used as a procedural sedative/analgesic agent, is the ONLY agent that can be administered by non-anesthetist RNs via the inhalation route.)

2. Administration of sedation/analgesia for the purpose of intubation, including Rapid-Sequence Intubation (RSI), is within RN scope of practice with specific education, competence, and policies and procedures as detailed in the NCBON RSI Position Statement.

3. Administration of medications for moderate to deep sedation/analgesia of already-intubated, critically ill clients is within RN scope of practice and is not limited by the constraints of this Position Statement.

4. The following are within scope of practice for both RNs and LPNs and are not limited by the constraints of this Position Statement:
   - Administration of Analgesia for pain control without sedatives,
   - Administration of Minimal Sedation/Analgesia (Anxiolysis),
   - Administration of Topical/Local Anesthesia, and,
   - Administration of Sedation/Analgesia solely for the purpose of managing altered mental status.

Definitions:

American Society of Anesthesiologists (ASA) Physical Status Classification –

a. Class I – normally healthy client
b. Class II – client with mild systemic disease
c. Class III – client with severe systemic disease
d. Class IV – client with severe systemic disease that is constant threat to life
e. Class V – a moribund client who is not expected to survive 24 hours with or without the procedure.

Anesthetic Agents – medications that, when administered, cause partial or complete loss of sensation, with or without loss of consciousness

Computer-assisted personalized sedation/analgesia devices - integrated drug infusion pump and physiological client monitoring system that administers medication (i.e., propofol) intravenously for initiation and maintenance of minimal to moderate procedural sedation/analgesia. The device continually monitors client

physiological parameters and responsiveness, detects signs associated with over-sedation/analgesia, and adjusts the medication delivery rate to limit the depth of sedation/analgesia.

Deep Sedation/Analgesia – drug-induced depression of consciousness during which clients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The client's ability to independently maintain ventilatory function may be impaired. Clients may require assistance to maintain a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia – drug-induced loss of consciousness during which clients are not arousable, even by painful stimulation. The client's ability to independently maintain ventilatory function is often impaired. Clients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Immediately available – present on site in the unit of care and not otherwise engaged in any other uninterruptible procedure or task.

Minimal Sedation/Analgesia (Anxiolysis) – drug-induced state during which clients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Administration of medications appropriate for this purpose include benzodiazepines and opioids, but not anesthesia agents, and is within the scope of practice for both RNs and LPNs.

Moderate (Conscious) Sedation/Analgesia – drug-induced depression of consciousness during which the client responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required for the client to maintain a patent airway and adequate spontaneous ventilation. Cardiovascular function is usually maintained.

Monitored Anesthesia Care (MAC) – anesthesia care that includes the monitoring of the client by a practitioner who is qualified to administer anesthesia. Indications for MAC depend on the nature of the procedure, the client's clinical condition, and/or the potential need to convert to a general or regional anesthetic.

Procedural Sedation/Analgesia – technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows the client to tolerate unpleasant procedures while maintaining cardiovascular and respiratory function.

Rapid-Sequence Intubation (RSI) – airway management technique in which potent sedative or induction agent is administered simultaneously with a paralyzing dose of a neuromuscular blocking agent to facilitate rapid tracheal intubation. The technique includes specific protection against aspiration of gastric contents, provides excellent access to the airway for intubation, and permits pharmacologic control of adverse responses to illness, injury, and the intubation itself.

(For details see NCBON RSI Position Statement.)

Regional Anesthesia – delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of

consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required.

Rescue Capacity – requires the competency to manage a compromised airway, provide adequate oxygenation and ventilation, and administer emergency medications and/or reversal agents to clients whose level of sedation becomes deeper than intended.

Sedating Agent – medication that produces calmness, relaxation, reduced anxiety, and sleepiness when administered.

Topical or Local Anesthesia – application or injection of a medication or combination of medications to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which are also not anesthesia, despite the name.

RN Education and Competency Requirements for Procedural Sedation/Analgesia:

Education, training, experience, and validation of initial and ongoing competencies appropriate to RN responsibilities, procedures performed, and the client/population must be documented and maintained. (Note: Employing agency determines frequency with which ongoing competencies are re-validated.)

A. The RN administering moderate and/or deep procedural sedation/analgesia must possess in-depth knowledge of and validated competency to apply the following in practice:

1. Anatomy & physiology, including principles of oxygen delivery, transport and uptake, cardiac dysrhythmia recognition and interventions, and complications related to moderate and deep procedural sedation/analgesia;

2. Pharmacology of sedation, analgesia, and anesthetic agent(s) administered singly or in combination, including appropriate administration routes, drug actions, drug interactions, side effects, contraindications, reversal agents (as applicable), and untoward effects;

3. Airway management skills required to rescue a patient from sedation/analgesia level deeper than intended and to manage a compromised airway or hypoventilation (i.e., establish an open airway, head-tilt, chin lift, use of bag-valve mask, and oral and nasal airways); and,

4. Advanced Cardiac Life Support (ACLS) and/or Pediatric Advanced Life Support (PALS) certification including dysrhythmia recognition, cardioversion/defibrillation, and emergency resuscitation appropriate to the status of the client/population.

B. In addition, the RN administering moderate and/or deep procedural sedation/analgesia must possess validated practice competencies needed to:

5. Assess total client care needs before and during the administration of moderate or deep procedural sedation/analgesia and throughout the recovery phase, including implementing nursing care strategies appropriate to the client's ASA Physical Status Classification as determined by Physician, CRNA, NP, or PA;

6. Perform appropriate physiologic measurements and evaluation of respiratory rate; oxygen saturation; carbon dioxide level; blood pressure; cardiac rate and rhythm; and level of consciousness;
7. Assess, identify, and differentiate the levels of sedation/analgesia and provide monitoring appropriate to the client's desired and actual level of sedation/analgesia;
8. Identify and implement appropriate nursing interventions in the event of sedation/analgesia complications, untoward outcomes, and emergencies; and,
9. Assess sedation/analgesia recovery including the use of a standardized discharge scoring system.

Agency Responsibilities in Procedural Sedation/Analgesia:

Based on client care needs, facility regulations, accreditation requirements, applicable standards, personnel, equipment, and other resources, each employing agency determines IF the administration of moderate and/or deep procedural sedation/analgesia by non-anesthetist RNs is authorized in their setting. If administration of moderate and/or deep procedural sedation/analgesia by non-anesthetist RNs IS permitted, the Director of Nursing or lead RN in the employing agency, in collaboration with anesthesia providers and other appropriate agency personnel, is responsible for assuring that written policies and procedures, including but not limited to the following, are in place to address:

1. Credentialing requirements for non-anesthesiologist Physicians, NPs, and PAs approved to perform moderate and/or deep procedural sedation/analgesia;
2. Required documentation of initial and ongoing RN education and competency validation in the manner and at the frequency specified by agency policy;
3. Physician, CRNA, NP, or PA (not the non-anesthetist RN) responsibility for pre-procedure assessment of the client, including assessment and determination of ASA Physical Status Classification score;
4. Number and qualifications of personnel to be present in the room during RN administration of moderate and/or deep procedural sedation/analgesia and requirement that designated personnel are competent to rescue the client should the airway or hemodynamic status be compromised;
5. Requirement that the Physician, CRNA, NP, or PA ordering RN-administered moderate procedural sedation/analgesia be physically present in the procedure area and immediately available during the time moderate procedural sedation/analgesia is administered in order to respond and implement emergency protocols in the event level of sedation deepens or another emergency occurs;
6. Requirement that the Physician, CRNA, NP, or PA ordering RN-administered deep procedural sedation/analgesia be physically present at the bedside throughout the time deep sedation/analgesia is administered in order to respond in the event of an emergency;
7. Requirement that the RN responsible for sedation/analgesia administration and monitoring of a client receiving moderate or deep sedation/analgesia will NOT assume other responsibilities which would leave

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the client unattended, thereby jeopardizing the safety of the client;

8. Specification of nursing care responsibilities for client assessment, monitoring, medication administration, potential complications, and documentation during moderate and/or deep procedural sedation/analgesia;
9. Specification of medications approved to be ordered and administered by RNs for moderate and/or deep procedural sedation/analgesia, including dosage limits as appropriate;

10. Specification of emergency protocol(s) including immediate on-site availability of resuscitative equipment, medications, and personnel; and

11. Requirement that age and size-appropriate procedural equipment, emergency resuscitation equipment, and medications, as well as personnel qualified to provide necessary emergency measures, such as intubation and airway management, be readily available during moderate and/or deep procedural sedation/analgesia.

    Age and size-appropriate equipment includes, but is not limited to:

    - blood pressure cuff and stethoscope
    - cardiac monitor and defibrillator
    - oxygen and suction devices
    - pulse oximetry and capnography
    - positive pressure ventilation equipment
    - intravenous administration devices & fluids
    - basic and advanced airway management devices
    - medications including sedatives, analgesics, reversal agents for opioids or benzodiazepines, and resuscitation drugs

Note: RNs retain responsibility and accountability for direct client assessment, intervention, and evaluation throughout the administration of moderate or deep procedural sedation/analgesia. Mechanical monitoring and medication administration devices (e.g., cardiac monitors, infusion pumps, and computer-assisted personalized sedation/analgesia devices) do not replace, but rather support, the RN's assessment and evaluation of client status.

Note: Pulse oximetry measures oxygenation, not ventilation. In the presence of supplemental oxygen, arterial oxygen desaturation as measured by pulse oximetry may represent a delayed sign of hypoventilation. For this reason, monitoring pulse oximetry is not a substitute for direct observation of patient ventilatory function. Capnography may be able to detect hypoventilation before pulse oximetry indicates oxygen desaturation and has been shown to be a more sensitive gauge of hypoventilation than visual observation.

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RN Role in Moderate and Deep Procedural Sedation/Analgesia:

1. The administration and monitoring of sedating and anesthetic agents to produce moderate or deep procedural sedation/analgesia for non-intubated adult and pediatric clients undergoing therapeutic, diagnostic, or surgical procedures is within the non-anesthetist RN scope of practice.

2. The RN must be educationally prepared; clinically competent; permitted to administer moderate and/or deep procedural sedation/analgesia by agency written policies and procedures; and not prohibited from doing so by facility-focused laws, rules, standards, and policies.

3. A qualified anesthesia provider (anesthesiologist or CRNA) or appropriately credentialed attending Physician, NP, or PA must assess client, determine ASA Physical Status Classification, select, and order the sedative/anesthetic agents to be administered; intended level of sedation/analgesia must be clearly communicated.

4. The RN is accountable for ensuring that moderate and/or deep procedural sedation/analgesia orders implemented are consistent with the current standards of practice and agency policies and procedures.

5. The RN accepts the assignment to administer ordered moderate or deep procedural sedation/analgesia only if competent and the practice setting has provided the age and size-appropriate equipment, medications, personnel, and related resources needed to assure client safety.

6. The RN administers <u>moderate</u> procedural sedation/analgesia to adult and pediatric clients only if a Physician, CRNA, NP, or PA credentialed by the facility in <u>moderate</u> procedural sedation/analgesia, and competent in airway management, is <u>physically present in the procedure area and immediately available</u> in order to respond and implement emergency protocols in the event level of sedation deepens or another emergency occurs.

7. The RN administers <u>deep</u> procedural sedation/analgesia to adult and pediatric clients only if a Physician, CRNA, NP, or PA credentialed by the facility in <u>deep</u> procedural sedation/analgesia, and competent in intubation and airway management, is <u>present at the bedside</u> in order to respond to any emergency.

8. The RN role in moderate and deep procedural sedation/analgesia is dedicated to the continuous and uninterrupted monitoring of the client's physiologic parameters and administration of medications ordered.

9. The administration of all medications via any appropriate route (including Nitrous Oxide via inhalation) for the purpose of moderate or deep procedural sedation/analgesia is within RN scope of practice. Medications, including *Etomidate, Propofol, Ketamine, Fentanyl, and Midazolam,* administered for moderate and/or deep procedural sedation/analgesia purposes, if ordered by Physician, CRNA, NP, PA, or

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other credentialed health care practitioner, and allowed by agency policy, is not prohibited provided the appropriate indications and precautions are in place.

LPN Role in Moderate and Deep Procedural Sedation/Analgesia: Given the level of independent nursing assessment, decision-making, and evaluation required for the safe care and management of clients undergoing therapeutic, diagnostic, and surgical procedures, the administration of sedation/anesthetic agents for the purposes of moderate or deep procedural sedation/analgesia is **beyond** LPN scope of practice.

RN and LPN Role in Regional Anesthesia: Regional anesthesia requires anesthetic agent delivery at a specific level of the spinal cord and/or to peripheral nerves, including epidurals, spinals, and other central neuraxial nerve blocks, when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. In these situations the positioning and stabilization of the client receiving regional anesthesia is sometimes challenging and the provider performing the procedure may need mechanical assistance from the nurse (RN or LPN) to attach and/or push the medication syringe plunger while personally maintaining appropriate positioning of the medication delivery device.

In such situations, the nurse may provide the needed manual support by functioning as the "third hand" of the provider. When acting as the provider's "third hand", the nurse is not accepting responsibility for administration of regional anesthesia, which is **beyond** both RN and LPN scope of practice. Instead, the provider retains full responsibility for the appropriate medication administration and accountability for outcomes.

Note:
1) This "third hand" specification does not include the administration of anesthetic agents by the non-anesthetist
nurse in any other situation. It is not permissible for the RN or LPN to function as the "third hand" of, or to provide only manual support or mechanical assistance to, a provider in the administration of moderate or deep procedural sedation/analgesia. To do so leaves the provider with responsibility for both performing the procedure and monitoring the patient. Moderate and/or deep procedural sedation/analgesia requires careful monitoring by a dedicated person. Therefore, the RN who administers moderate or deep sedation (this is beyond LPN scope of practice) is providing a nursing intervention and retains full accountability and responsibility for his/her actions. The RN functioning in this capacity must meet the Moderate/Deep Procedural Sedation education and competence requirements as delineated in this Position Statement.

2) It is within RN scope of practice to administer ordered additional or subsequent medication doses through a pre-established, indwelling epidural/caudal device per provider order. This constitutes RN medication administration for which the RN retains full responsibility and accountability. This is not within LPN scope of practice and is not considered manual or "third hand" assistance.

References:

21 NCAC 36.0224 Components of Nursing Practice for the Registered Nurse
21 NCAC 36.0225 Components of Nursing Practice for the Licensed Practical Nurse

American Association of Nurse Anesthetists (AANA) – www.aana.com– Resources section provides specific policy considerations for Registered Nurses Engaged in the Administration of Sedation/Analgesia
American Association of Moderate Sedation Nurses (AAMSN) – www.aamsn.org – Resources section provides information on Certified Sedation Registered Nurses (CSRN).

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