Novant Health Asheville Medical Center, LLC
CON for a New Acute Care Hospital in Buncombe County
Project ID B-012520-24
Opposition on Behalf of MH Mission Hospital, LLLP

Introduction:

The 2024 SMFP identifies a need for 26 acute care beds in the acute care planning area that includes Buncombe, Graham, Madison, and Yancey Counties. The need was generated by the high occupancy of Mission Hospital and the high acuity patients it serves as the only operational acute care provider in the service area composed of Buncombe County and three additional small, rural counties that each do not have an acute care hospital. Mission Hospital is the regional tertiary medical center and, as a result, cares for the defined service area as well as the entirety of Western North Carolina and beyond. In response to the demand for its high-acuity and specialized ICU and medical/surgical services, Mission Hospital has applied for the addition of 26 beds on its existing campus to address these specific needs. (See Project ID #B-12518-24.)

Two other applicants have applied for the 26 identified beds. Both Novant Health Asheville Medical Center, LLC ("Novant" or "NH Asheville"), Project ID B-012520-24, and AdventHealth Asheville, Inc. ("AdventHealth"), Project ID B-012526-24 have submitted applications to the Department in response to the published need. Novant proposes a 26-bed acute care hospital that is cancer focused. AdventHealth proposes to add 26-beds to its newly approved hospital to be constructed in Weaverville, Buncombe County through a change of scope application.

Throughout much of its application, Novant proposes a cancer-focused 26 acute-care bed hospital. However, in some places it also refers to itself as a cancer and surgical focused hospital because it has "partnered" with Messino Cancer Center ("MCC") and Novant Health - Surgical Partners Biltmore ("NHSPB") and uses the historical utilization of these two practices as its basis to demonstrate need for the proposed hospital. MCC is a regional oncology and hematology group practice with 31 physicians and advanced practice providers with multiple clinics in Buncombe, Macon, Jackson, and Mitchell Counties. NHSPB is a multi-specialty surgical group practice with ten surgeons and advanced practice providers affiliated with Novant Health that provides general, oncologic, and other specialty surgeries. Thus, for all intents and purposes, Novant has planned a hospital to accommodate the needs of two physician practices and not the broader needs of the service area population.

Novant's utilization methodology and assumptions are the best indicator of its intended patient population, which is largely limited to patients already served by MCC and NHSPB. Novant describes its project as both a specialized cancer hospital and a general community hospital with surgical and cancer services. However it chooses to label itself, its description indicates that it is a small 26-bed acute care hospital serving limited DRGs with one licensed operating room ("OR") and general diagnostic equipment. Note that Novant cannot and will not offer radiation therapy. It does not propose a fixed MRI, the most common imaging equipment used to diagnose, stage, and restage cancer, and it cannot offer PET/CT, another common cancer-focused imaging service. NH Asheville will offer infusion therapy services, but this service alone does not require CON review and NH Asheville states it has already submitted an exemption letter for an MOB that will house an outpatient infusion service. Thus, the proposed cancer-focused hospital will offer a very limited range of cancer services in actuality.

While NH Asheville labels itself a cancer-focused hospital, it fails to describe any specific cancer services that will be offered or provided and mainly uses discussion of this service line to bring up alleged issues with the provision of cancer care at Mission Hospital. As will be shown, NH Asheville's supporter Messino

has driven much of the recent change in cancer services in the service area, and the suggestion of referrals out of the region are far overstated.

In addition, Novant proposes to acquire one licensed operating room from Outpatient Surgery Center of Asheville ("OSCA") and transfer the existing outpatient operating room from its freestanding ASC to the proposed hospital. This is problematic from several perspectives. It shifts surgeries from a more cost-efficient location, a freestanding ASC, to a more costly hospital care environment. The proposed relocated OR will serve fewer patients overall within a more limited service area.

Novant's application is largely based on serving cancer and surgical patients that have medical homes at Messino Cancer Center and Novant Health Surgical Partners - Biltmore. Its limitation to and emphasis of these two groups is concerning, and thus, many of its related utilization assumptions are unfounded. This results in inpatient bed utilization that is both highly overstated and financially infeasible for the long term. Its surgical, ED, and ancillary assumptions and resulting projections are equally flawed. In addition, its service area does not make sense because it reflects the patients of just two practices - MCC and NHSPB. Across almost all criteria, Novant's project is flawed and is non-conforming. For these reasons and others discussed below, its application must be denied.

Criterion (1) Novant's Application is Inconsistent with the SMFP and Policy GEN-3

Novant's proposal is inconsistent with the acute care bed need determination in the 2024 State Medical Facilities Plan. First, Novant's proposal demonstrates that it does not intend to increase access to acute care services to the SMFP defined service area of Buncombe, Madison, Yancey, and Graham Counties, but only to the patients of MCC and NHSPB. Novant's entire service area is defined by the patient origin statistics of these two referring entities. As a result, the service area is overly broad and ambiguously identified. Moreover, it is not meaningful for a general provider of low acuity hospital services to include surgical procedures and largely undefined cancer care for low acuity DRGs.

Novant's proposal is also inconsistent with Policy GEN-3 with respect to maximizing healthcare value for the resources expended. Novant proposes to relocate and replace a relatively new OR implemented and used since 2021 as a dedicated freestanding outpatient OR in the Outpatient Surgery Center of Asheville ("OSCA"). Upon relocation, the ASF will use this newly constructed operating room as an unlicensed procedure room to do the very same surgical cases. The transfer of an operating room from the Outpatient Surgery Center of Asheville ("OSCA") to the proposed facility for use as a hospital-based inpatient/outpatient operating room diminishes, if not destroys, the intent and purpose of the SMFP OR Need Methodology to differentiate between dedicated outpatient, inpatient, and shared operating rooms in the acute care setting.

Novant describes its proposed hospital as a cancer-focused, inpatient hospital. However, it does not design or upfit its hospital beyond the general capabilities of a small community hospital. Its equipment offerings are standard: CT, mobile MRI, x-ray/fluoro, and nuclear medicine/SPECT imaging. It does not include any diagnostic and/or treatment modalities typically used by oncologists to include PET or radiation therapy (LINAC). In fact, Novant intends to construct an MOB on the hospital campus that will include a vault for future LINAC placement, a 20-chair infusion suite, and outpatient mammography. Through its health planning, Novant acknowledges that cancer care is largely an outpatient service. However, its narrative creates an unjustified need for inpatient cancer care so it can use historical MCC patients as a basis to build its utilization model.

NH Asheville Has Not Demonstrated that it is a Qualified Applicant

The 2024 SMFP includes a requirement that an applicant for a new acute care hospital must provide:

> *"medical and surgical services on a daily basis within at least five of the following major diagnostic categories (MDC) recognized by the Centers for Medicare & Medicaid Services listed below:*
>
> *MDC 1: Diseases and disorders of the nervous system*
> *MDC 2: Diseases and disorders of the eye*
> *MDC 3: Diseases and disorders of the ear, nose, mouth, and throat*
> *MDC 4: Diseases and disorders of the respiratory system*
> *MDC 5: Diseases and disorders of the circulatory system*
> *MDC 6: Diseases and disorders of the digestive system*
> *MDC 7: Diseases and disorders of the hepatobiliary system and pancreas*
> *MDC 8: Diseases and disorders of the musculoskeletal system and connective tissue*
> *MDC 9: Diseases and disorders of the skin, subcutaneous tissue, and breast*
> *MDC 10: Endocrine, nutritional, and metabolic diseases and disorders*
> *MDC 11: Diseases and disorders of the kidney and urinary tract*
> *MDC 12: Diseases and disorders of the male reproductive system*
> *MDC 13: Diseases and disorders of the female reproductive system*
> *MDC 14: Pregnancy, childbirth, and the puerperium*
> *MDC 15: Newborns/other neonates with conditions originating in the perinatal period*
> *MDC 16: Diseases and disorders of the blood and blood-forming organs and immunological disorders*
> *MDC 17: Myeloproliferative diseases and disorders and poorly differentiated neoplasms*
> *MDC 18: Infectious and parasitic diseases*
> *MDC 19: Mental diseases and disorders*
> *MDC 20: Alcohol/drug use and alcohol/drug-induced organic mental disorders*
> *MDC 21: Injury, poisoning and toxic effects of drugs*
> *MDC 22: Burns*
> *MDC 23: Factors influencing health status and other contacts with health services*
> *MDC 24: Multiple significant trauma*
> *MDC 25: Human immunodeficiency virus infections*
>
> *2024 SMFP – age 34-35*

As has been the precedent by other new acute care hospital applicants, a quantitative methodology has been provided to support that the applicant is a qualified applicant under this provision. NH Asheville does not provide any projection by DRG or MDC to demonstrate that it meets this requirement.

Moreover, the DRGs referenced in Exhibit C-1.2 (included in **Attachment A**) of Novant's application clearly demonstrate that its hospital is not limited to oncologic procedures and diagnoses. It is unclear how the DRG list was determined as it includes wide-ranging patient types for which NH Asheville does not have any referral support or clinical experience. Messino physicians are oncologists and NHSPB is a small six-person practice covering only three surgical specialties as shown in **Figure 1**:

Figure 1
Novant Health Surgical Partners - Biltmore

Colon and Rectal Surgery	2
Endocrine Surgery	1
Complex General and Oncology Surgery	3

Source: Practice website accessed 7-14-2024

There is no meaningful indication of any other physician practices that would refer to NH Asheville. Thus, the broader DRG list is illogical and unsupported. A number of examples are provided below in **Figure 2**:

Figure 2
DRGs That Are Inappropriate for NH Asheville Limited Medical Specialties

MDC 1: *Diseases and disorders of the nervous system*

MCC and NHSPB Do Not Have a Neurosurgeon but NH Asheville Includes these Neurosurgery DRGs

DRG	MDC	Med/Surg	DRG Description
23	1	SURG	CRANIOTOMY WITH MAJOR DEVICE IMPLANT OR ACUTE COMPLEX CNS PRINCIPAL DIAGNOSIS WITH MCC
28	1	SURG	SPINAL PROCEDURES WITH MCC

MCC and NHSPB Do not Have a Neurologist but Include these Neurology DRGs

DRG	MDC	Med/Surg	DRG Description
70	1	MED	NONSPECIFIC CEREBROVASCULAR DISORDERS WITH MCC
73	1	MED	CRANIAL AND PERIPHERAL NERVE DISORDERS WITH MCC
74	1	MED	CRANIAL AND PERIPHERAL NERVE DISORDERS WITHOUT MCC
81	1	MED	NONTRAUMATIC STUPOR AND COMA WITHOUT MCC
82	1	MED	TRAUMATIC STUPOR AND COMA >1 HOUR WITH MCC
85	1	MED	TRAUMATIC STUPOR AND COMA <1 HOUR WITH MCC
92	1	MED	OTHER DISORDERS OF NERVOUS SYSTEM WITH CC
93	1	MED	OTHER DISORDERS OF NERVOUS SYSTEM WITHOUT CC/MCC

MCC and NHSPB Do Not Have Neurologist or Infectious Disease Specialist but Include these DRGs

DRG	MDC	Med/Surg	DRG Description
94	1	MED	BACTERIAL AND TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM WITH MCC
97	1	MED	NON-BACTERIAL INFECTION OF NERVOUS SYSTEM EXCEPT VIRAL MENINGITIS WITH MCC
98	1	MED	NON-BACTERIAL INFECTION OF NERVOUS SYSTEM EXCEPT VIRAL MENINGITIS WITH CC

MDC 2: Diseases and disorders of the eye

MCC and NHSPB Do Not Have an Ophthalmologist or Neurologist but NH Asheville Includes these DRGs

DRG	MDC	Med/Surg	DRG Description
113	2	SURG	ORBITAL PROCEDURES WITH CC/MCC
123	2	MED	NEUROLOGICAL EYE DISORDERS

MDC 3: Diseases and disorders of the ear, nose, mouth, and throat

MCC and NHSPB Do Not Have an ENT or Oral Surgeon
but NH Asheville Includes these DRGs

DRG	MDC	Med/Surg	DRG Description
137	3	SURG	MOUTH PROCEDURES WITH CC/MCC
140	3	SURG	MAJOR HEAD AND NECK PROCEDURES WITH MCC
141	3	SURG	MAJOR HEAD AND NECK PROCEDURES WITH CC
142	3	SURG	MAJOR HEAD AND NECK PROCEDURES WITHOUT CC/MCC
144	3	SURG	OTHER EAR, NOSE, MOUTH AND THROAT O.R. PROCEDURES WITH CC
145	3	SURG	OTHER EAR, NOSE, MOUTH AND THROAT O.R. PROCEDURES WITHOUT CC/MCC
146	3	MED	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITH MCC
147	3	MED	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITH CC
148	3	MED	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITHOUT CC/MCC
157	3	MED	DENTAL AND ORAL DISEASES WITH MCC
158	3	MED	DENTAL AND ORAL DISEASES WITH CC

MDC 4: Diseases and disorders of the respiratory system

MCC and NHSPB Do Not Have a Pulmonologist
but NH Asheville Includes these Medical DRGs
The Proposed NH Ashville Hospital will NOT be a Trauma Center

DRG	MDC	Med/Surg	DRG Description
183	4	MED	MAJOR CHEST TRAUMA WITH MCC
187	4	MED	PLEURAL EFFUSION WITH CC
188	4	MED	PLEURAL EFFUSION WITHOUT CC/MCC
189	4	MED	PULMONARY EDEMA AND RESPIRATORY FAILURE
190	4	MED	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH MCC
191	4	MED	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH CC
193	4	MED	SIMPLE PNEUMONIA AND PLEURISY WITH MCC
194	4	MED	SIMPLE PNEUMONIA AND PLEURISY WITH CC
196	4	MED	INTERSTITIAL LUNG DISEASE WITH MCC
197	4	MED	INTERSTITIAL LUNG DISEASE WITH CC
198	4	MED	INTERSTITIAL LUNG DISEASE WITHOUT CC/MCC
200	4	MED	PNEUMOTHORAX WITH CC
204	4	MED	RESPIRATORY SIGNS AND SYMPTOMS
205	4	MED	OTHER RESPIRATORY SYSTEM DIAGNOSES WITH MCC
206	4	MED	OTHER RESPIRATORY SYSTEM DIAGNOSES WITHOUT MCC
207	4	MED	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT >96 HOURS
208	4	MED	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT <=96 HOURS

MDC 8: Diseases and disorders of the musculoskeletal system and connective tissue

MCC and NHSPB Do Not Have an Orthopedic Surgeon but NH Asheville Includes these DRGs

DRG	MDC	Med/Surg	DRG Description
456	8	SURG	SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH MCC
459	8	SURG	SPINAL FUSION EXCEPT CERVICAL WITH MCC
492	8	SURG	LOWER EXTREMITY AND HUMERUS PROCEDURES EXCEPT HIP, FOOT, AND FEMUR WITH MCC
501	8	SURG	SOFT TISSUE PROCEDURES WITH CC
502	8	SURG	SOFT TISSUE PROCEDURES WITHOUT CC/MCC
512	8	SURG	SHOULDER, ELBOW OR FOREARM PROCEDURES, EXCEPT MAJOR JOINT PROCEDURES WITHOUT CC/MCC
515	8	SURG	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITH MCC
516	8	SURG	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITH CC
517	8	SURG	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITHOUT CC/MCC
536	8	MED	FRACTURES OF HIP AND PELVIS WITHOUT MCC
540	8	MED	OSTEOMYELITIS WITH CC
551	8	MED	MEDICAL BACK PROBLEMS WITH MCC
552	8	MED	MEDICAL BACK PROBLEMS WITHOUT MCC
556	8	MED	SIGNS AND SYMPTOMS OF MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITHOUT MCC
557	8	MED	TENDONITIS, MYOSITIS AND BURSITIS WITH MCC
560	8	MED	AFTERCARE, MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITH CC
562	8	MED	FRACTURE, SPRAIN, STRAIN AND DISLOCATION EXCEPT FEMUR, HIP, PELVIS AND THIGH WITH MCC
564	8	MED	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE DIAGNOSES WITH MCC

MDC 11: Diseases and disorders of the kidney and urinary tract
MDC 12: Diseases and disorders of the male reproductive system

MCC and NHSPB Do Not Have a Urologist but NH Asheville Includes these DRGs:

DRG	MDC	Med/Surg	DRG Description
665	11	SURG	PROSTATECTOMY WITH MCC
666	11	SURG	PROSTATECTOMY WITH CC
667	11	SURG	PROSTATECTOMY WITHOUT CC/MCC
668	11	SURG	TRANSURETHRAL PROCEDURES WITH MCC
669	11	SURG	TRANSURETHRAL PROCEDURES WITH CC
670	11	SURG	TRANSURETHRAL PROCEDURES WITHOUT CC/MCC
671	11	SURG	URETHRAL PROCEDURES WITH CC/MCC
672	11	SURG	URETHRAL PROCEDURES WITHOUT CC/MCC
673	11	SURG	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITH MCC
674	11	SURG	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITH CC
675	11	SURG	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITHOUT CC/MCC
682	11	MED	RENAL FAILURE WITH MCC
683	11	MED	RENAL FAILURE WITH CC
684	11	MED	RENAL FAILURE WITHOUT CC/MCC
689	11	MED	KIDNEY AND URINARY TRACT INFECTIONS WITH MCC
690	11	MED	KIDNEY AND URINARY TRACT INFECTIONS WITHOUT MCC
694	11	MED	URINARY STONES WITHOUT MCC
695	11	MED	KIDNEY AND URINARY TRACT SIGNS AND SYMPTOMS WITH MCC
696	11	MED	KIDNEY AND URINARY TRACT SIGNS AND SYMPTOMS WITHOUT MCC
698	11	MED	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH MCC
699	11	MED	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH CC
700	11	MED	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITHOUT CC/MCC
707	12	SURG	MAJOR MALE PELVIC PROCEDURES WITH CC/MCC
708	12	SURG	MAJOR MALE PELVIC PROCEDURES WITHOUT CC/MCC
709	12	SURG	PENIS PROCEDURES WITH CC/MCC
710	12	SURG	PENIS PROCEDURES WITHOUT CC/MCC
711	12	SURG	TESTES PROCEDURES WITH CC/MCC
713	12	SURG	TRANSURETHRAL PROSTATECTOMY WITH CC/MCC
714	12	SURG	TRANSURETHRAL PROSTATECTOMY WITHOUT CC/MCC
717	12	SURG	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES EXCEPT MALIGNANCY WITH CC/MCC
718	12	SURG	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES EXCEPT MALIGNANCY WITHOUT CC/MCC
728	12	MED	INFLAMMATION OF THE MALE REPRODUCTIVE SYSTEM WITHOUT MCC
729	12	MED	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES WITH CC/MCC

MDC 13: Diseases and disorders of the female reproductive system

MCC and NHSPB Do Not Have a Gynecologist but NH Asheville Includes these DRGs:

DRG	MDC	Med/Surg	DRG Description
742	13	SURG	UTERINE AND ADNEXA PROCEDURES FOR NON-MALIGNANCY WITH CC/MCC
743	13	SURG	UTERINE AND ADNEXA PROCEDURES FOR NON-MALIGNANCY WITHOUT CC/MCC
744	13	SURG	D&C, CONIZATION, LAPAROSCOPY AND TUBAL INTERRUPTION WITH CC/MCC
746	13	SURG	VAGINA, CERVIX AND VULVA PROCEDURES WITH CC/MCC
747	13	SURG	VAGINA, CERVIX AND VULVA PROCEDURES WITHOUT CC/MCC
748	13	SURG	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES
749	13	SURG	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES WITH CC/MCC
760	13	MED	MENSTRUAL AND OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS WITH CC/MCC

The inclusion of the above DRGs for which there is no appropriate referring or operating physician specialty at MCC or NHSPB raises questions about whether NH Asheville will be able to serve medical/surgical patients daily within at least five MDCs. The applicant has not shown this will be true in any quantitative manner. Moreover, the inclusion of these DRGs raises numerous questions about the utilization projections for the proposed NH Asheville Hospital. NH Asheville has not documented that it is a qualified applicant and should be found non-conforming with Criterion (1).

As will be discussed in Criterion (3), it does not appear that NH Asheville used this DRG list to generate its utilization projections. It appears it instead generated its utilization projections from patient admissions generated by Messino Cancer Center and NHSPB. There is truly no documentation that the hospital would provide daily medical and surgical services in at least five MDCs.

<u>NH Asheville's Proposed Service Area is Overly Broad</u>

The 2024 SMFP defines the service area for the project to be Buncombe, Graham, Madison, and Yancey Counties. However, NH Asheville defines its primary service area to be the SMFP counties previously listed plus Haywood County, Henderson County, McDowell County, and Macon County (See application page 40.). The inclusion of Macon County, located in far-western North Carolina, appears to only be relevant to the extent it is consistent with the claimed historical service areas of MCC and NHSPB.

Novant Health does not demonstrate any unique capabilities, enhanced clinical knowledge, or high-level staffing for its proposed cancer-focused hospital. Novant makes clear in its application that its service area is based entirely on historical patient origin of MCC and NHSPB.

> *"The service area for NH Ashville (sic) is based on the service area established by the SMFP and the patient origin of Messino Cancer Centers patients and the patient origin of NH Surgical Partners-Biltmore's patients who received hospital services in Buncombe County NH Asheville will provide. Inpatients appropriate for care at NH Asheville are defined by a set of MSDRGs reviewed by NH Cancer Institute physicians and staff. See Exhibit C-1.2 for these DRGs. As discussed in Section Q, the utilization projections for this application assume Messino Cancer Centers and NH Surgical Partners-Biltmore physicians will treat the majority of their clinically appropriate patients at NH Asheville for hospital-based care. These two practices have expressed support for this application and their intention to treat clinically appropriate patients at NH Asheville. See Exhibit C-*

1.15 and Exhibit C-1.16 for their letters. Therefore, it is appropriate to define the service area as the set of counties that account for the majority of these physicians' patients." – Pages 41 and 42

The DRGs referenced in Exhibit C-1.2 (included in **Attachment A**) of Novant's application clearly demonstrate that its hospital is not limited to oncologic procedures and diagnoses. Yet, it bases both its service area and its utilization largely on the patient origin and utilization of MCC. As shown in Novant's map on page 56 of its application, residents of Macon and Graham Counties must drive through at least three counties to reach Novant's proposed hospital in Buncombe County.

Novant's patient origin projections lack support for its assumptions. Inpatient services projections, which, by Novant's definition, should largely tie to MCC oncology patients and NHSPB inpatient surgical patients, show that almost twenty percent of inpatients are projected to originate from counties outside the eight-county service area. See NH Asheville application page 45. Theoretically, these are patients traveling from all over North Carolina to seek care at a 26-bed hospital with no unique services. It is unreasonable to assume that a small, 26-bed community hospital would draw from an eight-county service area, much less serve 20% of its patients from an even broader region.

NHSBP NH Asheville's outpatient surgical projections do not differ significantly from its inpatient service projections. See NH Asheville application page 45. Novant projects that more than 17% of outpatient surgical patients will originate outside of its eight-county service area. These patients are projected to be based on historical utilization of NHSPB. As NHSPB is a relatively small surgical practice with just six physicians, it is highly unlikely that this practice is drawing and serving this many patients outside of the eight service area counties. No patient origin information of NHSPB is provided to support such assumptions.

Novant's service area is unreasonable and unsupported.

The Operating Room Transfer from OSCA to NH-Asheville is Inconsistent with the Agency's Prior Approval and Intent as well as the SMFP OR Need Methodology

In 2018, the Orthopaedic Surgery Center of Asheville submitted a CON application pursuant to the 2018 SMFP to develop a new multispecialty ambulatory surgical facility ("ASF"), to be known as Asheville SurgCare with five operating rooms and two procedure rooms, by relocating the three operating rooms at Orthopaedic Surgery Center of Asheville and developing two additional operating rooms pursuant to the need identified in the 2018 SMFP. This facility is now known as Outpatient Surgery Center of Asheville ("OSCA") and currently houses the operating room that is proposed for sale and transfer to NH Asheville in this application.

The five operating rooms have been in operation less than three years, since approximately September 2021. The draft 2025 SMFP shows that OSCA is still operating five ambulatory operating rooms and has a deficit of 1.41 operating rooms. This indicates that OSCA has a current need for an additional 1.41 operating rooms—assuming they do not sell one of the current five to Novant. It is financially inefficient to convert this recently constructed and needed outpatient OR to a hospital-based OR. This OR was specifically approved by the CON Section based on the representations of OSCA that additional outpatient OR capacity was needed in Buncombe County. OSCA's plans to sell the OR to a new inpatient hospital suggests a failure to materially comply with the representations in its approved and implemented application.

For these reasons, the Novant application should be found non-conforming with Criterion (1).

NH Asheville Does not Conform with the Basic Principles Outlined in Policy GEN-3

Policy GEN-3: Basic Principles states:

"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."

Novant's project fails to conform with multiple aspects of Policy Gen-3: Basic Principles. Among them, this project fails to promote safety and quality, equitable access, to maximize healthcare value for resources expended, to project volumes that incorporate GEN-3 concepts in meeting the need identified in the SMFP, and to address the needs of all residents in the acute care planning area.

Safety and Quality

Novant fails to adequately describe the typical cancer inpatient that it intends to treat in its application. However, it references its cancer-focused services in all sections throughout the application. But its DRG listing in Exhibit C-1.2 includes numerous oncologic and non-oncologic diagnoses and procedures. Assuming it truly intends to operate as a cancer-focused hospital, it lacks the equipment and services necessary to make it a quality, specialized cancer facility. Specifically, it lacks fixed MRI, radiation therapy, and PET/CT, among other modalities and services.

Novant states that linear accelerator/radiation therapy (LINAC) treatment will be available through an affiliation with GenesisCare. If a cancer patient is inpatient, it indicates that this patient is acutely ill, as most cancer patients receive outpatient treatment and care. These patients will either be transported to the GenesisCare locations offering radiation oncology in Hendersonville, 9.5 miles from the proposed Novant Hospital, or the location in Asheville, 7.9 miles away from the proposed project. In addition, while mobile MRI will be offered full-time on-site, it will still be housed in a mobile unit that will require transport outside of the hospital structure. Again, this is not ideal for an acutely ill cancer patient.

In addition, Novant's total surgical projections indicate a need for 1.44 operating rooms to serve the patients projected in Year 3 of operation. Novant only proposes one operating room for its project. To address this deficiency, Novant states that its surgical unit will also have three unlicensed procedure rooms built to OR standards and that it will spread its surgical volume throughout these four rooms (p.181). As a result, most of Novant's surgeries will be performed in unlicensed procedure rooms. This is neither safe nor an indicator that quality is a priority for this project.

Novant proposes a cancer-focused hospital that has no convenient access to actual cancer-specific services and surgical services largely provided in unlicensed procedure rooms. This project is poorly defined and not in the best interest of the patients it intends to serve.

Equitable Access for Planning Area Residents

This project fails to promote equitable access and to address the needs of all residents in the identified acute care planning area that generated the bed need. As discussed briefly above, the 2024 SMFP identifies Buncombe, Madison, Yancey, and Graham Counties to be the service area with a need for additional acute care beds. However, NH Asheville projects a broad eight-county service area to meet a limited diagnostic need for the patients of two physician practices.

As a result, this project fails to enhance access for its SMFP defined service area. More than 45% of Novant's projected inpatients and surgical outpatients will originate outside of Buncombe, Madison, Yancey, and Graham Counties. Unlike Mission Hospital, which serves a broad regional area due to its trauma, specialty, and high acuity patients, it is unclear how NH Asheville will serve 45% of its patients from outside of the defined service area with a small, limited scope facility. See **Figure 3**.

Figure 3
Summary of NH Asheville Patient Origin

County	Inpatient	Outpatient Surgical	Outpatient Non-Surgical	Entire Facility
Buncombe	46.87%	46.00%	71.00%	65.18%
Henderson	10.82%	14.00%	8.00%	9.02%
Haywood	7.65%	7.00%	4.00%	4.79%
Madison	4.64%	4.52%	3.66%	3.88%
Macon	4.07%	3.01%	0.89%	1.53%
McDowell	3.66%	4.37%	2.07%	2.53%
Yancey	2.60%	3.01%	1.17%	1.55%
Graham	0.65%	0.50%	0.17%	0.27%
Other	19.04%	17.59%	9.04%	11.25%
Total	100.00%	100.00%	100.00%	100.00%
Outside SMFP Service Area	**45.24%**	**45.97%**	**24.00%**	**29.12%**

Source: NH Asheville application pages 44-47.

In addition, NH Asheville is expected to capture between 17% and 19% of its inpatients and surgical outpatients from counties outside of its eight-county service area, which as mentioned above is already too large and incongruous with the actual intended service area driving the bed need. Some migration from outside the defined service area is always expected, but this is unrealistic.

In addition, the service area is based on the historical utilization of two existing providers – Messino Cancer Center and Novant Health Surgical Partners-Biltmore. Novant does not consider demographic factors in determining the need and location for its proposed project, and it does not demonstrate any quantitative analysis of the need for cancer or surgical services in the service area. All quantitative analysis for these services is based on an estimate of shifted utilization from MCC and NHSPB. The needs of the SMFP service area, or even adjacent counties, are not considered in Novant's demonstration of the need for the project. Once Novant determines and identifies that MCC and NHSPB will be the primary referral sources for its Asheville hospital, it provides a general discussion of cancer incidence for the primary service area. However, it never provides a calculation or demonstration of the need for acute care, hospital-based cancer services that does not directly tie back to these two providers.

Maximizing Healthcare Value

In addition, Novant's proposed project does not maximize healthcare value for resources expended. Novant proposes to spend $249,475,340 to develop a 26-bed hospital with "a cancer focus" but without any specialized service offerings or equipment. Without any differentiating factors, other than a highly limited medical staff, the costly project is an unnecessary duplication of the two community hospitals already serving a similar service area and located minutes from the proposed project. AdventHealth Hendersonville ("AdventHealth Hendersonville") is less than 10 miles and 15 minutes from the proposed NH Asheville location. UNC Health Pardee Hospital ("Pardee") is located less than 14 miles and about 20 minutes from NH Asheville's proposed location. In addition, AdventHealth Asheville has been approved in Buncombe County and will also provide similar services. The costs related to developing and constructing another community hospital located directly between the existing area hospitals does not maximize healthcare value. In addition, as will be discussed in Criterion (5), Novant proposes one of the most expensive hospitals in the last five years.

The proposed relocation of an ASF OR coupled with the purchase and subsequent construction of a new hospital-based OR does not maximize healthcare value. The costly duplication of an OR that has been in operation for less than three years is also not cost effective. In this case, this one OR will incur costs for three separate transactions. First, costs were incurred for its construction and implementation at OSCA. Second, Novant must purchase the OR from OSCA before it can begin construction on its hospital. Finally, Novant will incur construction costs to build this OR again for hospital-based use. By the time this one operating room is used in the proposed hospital, it will have been paid for on three separate occasions in less than a decade. The low-cost benefits of an ASF are also undermined by shifting this OR to a more costly hospital-based environment. Please see additional discussion under Criterion (3a).

For the many reasons set forth above, NH Asheville's application does not meet the criteria set forth in Policy GEN-3: Basic Principles and cannot be approved.

Criterion (3) Novant Fails to Adequately Demonstrate Need for the Project

Novant does not adequately demonstrate the need for the proposed project and cannot be found conforming with Criterion (3). Among its deficiencies, the project is never fully defined. It claims to be a "cancer-focused hospital" and also a low-acuity hospital. The DRGs included in Exhibit C-1.2 (included herein as **Attachment A**) are expansive and are not limited to low-acuity inpatient cancer services and/or surgical procedures. It is unclear what procedures and services NH Asheville will actually offer that provide distinct benefits to service area patients. Novant's utilization projections are flawed across all services and cannot be reliably used in assessing the need for this project. Most importantly, Novant fails to assess and quantify the actual need for inpatient cancer services for the SMFP service area. A quantitative assessment of need as demonstrated below indicates that there is not a sufficient need for a focused 26-bed cancer/surgical hospital.

<u>The Population that Novant Proposes to Serve is Unclear, Inconsistent, and Poorly Defined</u>

Novant spends much of the application identifying its proposed project as a cancer-focused hospital (Executive Summary, pages 28, 34, and others). It also refers to itself as "cancer and surgical focused" (page 35), as well as an acute care hospital having the capability to offer many low acuity services. The DRGs presented in Exhibit C-1.2 to show the capabilities of the proposed hospital extend well beyond cancer and surgical diagnoses and procedures. It is difficult to ascertain the true service offerings of the Applicant based on the information presented. As stated on page 36, "While the scope of acute care services in this application focuses on the care patients with a cancer diagnosis routinely receive in a hospital-based setting, NH Asheville will provide high-quality care to all patients who come to the hospital." This

statement makes the project even less clear and highlights the amount of detail left out of the project description.

The cancer-focused services that Novant intends to offer cannot be identified by the information included in the application. Novant determines both its service area and its projected utilization based on the MCC and NHSPB 2023 inpatients to be "appropriate for care at NH Asheville."

> The service area for NH Ashville is based on the service area established by the SMFP[21] and the patient origin of Messino Cancer Centers patients and the patient origin of NH Surgical Partners-Biltmore's patients who received hospital services in Buncombe County NH Asheville will provide. Inpatients appropriate for care at NH Asheville are defined by a set of MSDRGs reviewed by NH Cancer Institute physicians and staff. See Exhibit C-1.2 for these DRGs.

Source: Application page 41

However, the list of MSDRG's that supposedly capture these patients contain DRGs that fall outside of inpatient cancer care and surgical treatment. See **Attachment A** for a copy of Exhibit C-1.2. As shown below, the DRGs included on the list include "those MSDRGs historically performed by physicians who have committed to treating their patients at NH Asheville **and** those that could be treated at NH Asheville based on NH's experience at its other hospitals."

> The Applicants assumed NH Asheville will see inpatients in a limited range of Medical Severity Diagnosis Related Groups (MSDRGs) during the first three years of operation, the Limited Acute Care (LAC) MSDRGs. Exhibit C-1.2 shows the MSDRGs classified as LAC along with their descriptions.
>
> Each MSDRG covers certain diagnoses and procedures. The list of MSDRGs was created in consultation with several NH Cancer Institute physicians and leaders. NH excluded all MSDRGs in the pediatrics, obstetrics, normal newborns, non-acute neonates, NICU, cardiac catheterization, and transplant service lines. The list was then narrowed to only include those MSDRGs historically performed by physicians who have committed to treating their patients at NH Asheville and those that could be treated at NH Asheville based on NH's experience at its other hospitals.

Source: Application page 36

This statement clarifies that the DRGs included in Exhibit C-1.2 of the application are not limited to only the DRGs associated with 2023 inpatient discharges of MCC and NHSPB determined appropriate for care at NH Asheville, which were used to determine the proposed service area and as the basis for the utilization projections. Novant does not include a specific list of DRGs limited to the 2023 inpatient and surgical discharges for MCC and NHSPB that were used to determine the service area and projected utilization.

The narrative description in Section C refers to both an inpatient cancer focus as well as a cancer and surgical focus, but it never identifies what patient diagnoses and types of care this entails, aside from the inpatient leukemia and lymphoma chemotherapy patients mentioned throughout the application. Most cancer patients do not routinely receive care in a hospital setting. Cancer trends have largely moved treatment and care outside of the hospital to an outpatient setting that is more affordable and convenient to access. Inpatient cancer services are often for those who are acutely ill, would not necessarily fall under a low-acuity DRG, and would need specialized, multi-disciplinary care. On pages 36 and 169, Novant states that it cannot accurately predict which subspecialist will be on staff. All references to Novant oncology subspecialists (Executive Summary pages 4 and CON page 35) describe remote access and not physicians who will be physically present and on staff. With multiple, conflicting service descriptions for the hospital and a varied DRG list of diagnoses and procedures that NH Asheville could appropriately treat, it is impossible to know or understand the real intent of the proposed project.

Novant's Projected Utilization is Vague and Flawed

Across all service lines, Novant's project is flawed, even without knowing the specific DRGs upon which its utilization projections are based.

Inpatient Hospital Services (Scope of Services, Basis, Steps 1-6)

Novant's scope of services demonstrates that it has not considered the actual needs of the SMFP service area. On page 162, "Scope of Inpatient Clinical Services…," Novant explains that it first assumed that NH Asheville would offer a limited range of services that consist of Limited Acute Care (LAC) MS-DRGs[1] it has deemed appropriate for NH Asheville. These are reflected in **Attachment A**. Novant's DRG Exhibit includes DRGs that are often tied to lower acuity level diagnoses and treatments, but is not limited to any specialized focus, including cancer and surgery, overriding its claims that this is a cancer-focused hospital.

Novant then clarifies that its utilization projections are not based on the total LAC DRGs described above, but on actual 2023 discharges of inpatients referred by MCC and NHSPB to Buncombe County and Henderson County hospitals with DRGs deemed appropriate for treatment at NH Asheville. Novant's entire basis for projecting its utilization is limited to the patients of two physician practices – MCC and NHSPB. It does not consider the list of DRGs it deems itself appropriate to serve (**Attachment A**) or the needs of the service area in its projections. Novant's methodology only focuses on serving the patients of these two practices. As noted above, the LAC DRG list provided is inconsistent with the specialties of MCC and NHSPB, which are highly limited.

Further, Novant fails to identify in its assumptions the actual DRGs it does use in its projections or any method it used to determine and validate their appropriateness for inclusion. As a result, it is impossible to verify that the discharges included in Step 1 are appropriate for inclusion or to determine the type of patients and procedures they include. The only specific inpatient description given throughout the application is inpatient chemotherapy for leukemia and lymphoma patients.

Step One quantitatively summarizes the total "appropriate" 2023 discharges and inpatient days described above for MCC and NHSPB. See below.

The table below shows the discharges and patient days from each physician group in the base year.

MCC and NHSPB Historical 2023 Base Year Volumes
Buncombe and Henderson County Hospitals

Physician Practice	Discharges	Inpatient Days
MCC	786	6,093
NHSBP	443	2,269
Total	**1,229**	**8,362**

Source: Inpatient HIDI Database. July 2022–December 2023. MCC (YE June 2023). NHSBP (YE Dec 2023).

NH Asheville CON application page 163.

As both MCC and NHSPB admit patients to Mission Hospital, Mission Hospital undertook an analysis to verify the number of actual patient admissions for MCC and NHSPB. This analysis does not support NH Asheville's projections. Mission Hospital searched both attending and operating physician fields in the

[1] "Limited Acute Care (LAC) MSDRGs" is not a technical term utilized by CMS to define a set of lower acuity DRGs. It is a term used by the Applicant to vaguely describe the type of DRGs appropriate for inpatient care at NH Asheville. It cannot be used to identify specific DRGs that Applicant uses in its projections and assumptions.

same data source that NH Asheville claims to rely upon and found that the discharges and patient day volumes were significantly lower than those identified by NH Asheville. Like NH Asheville's analysis, HIDI data was limited to exclude pediatrics, obstetrics, normal newborns, neonates and NICU, cardiac catheterization, and transplant services. The data was limited to just MCC and NHSPB physicians. In addition, the LAC DRG list was then applied to the MCC and NHSPB list of patients. The resulting patient base is much smaller than identified by Novant. In fact, this base of patients only has an average daily census of 20. This is 12.6% lower than the 7,304 patient days identified in **Figure 4**.

Figure 4
MCC and NHSPB Historial 2023 Base Year Volumes
Buncombe and Henderson County Hospitals
Only LAC DRGs as Defined by Novant

	Discharges	**Days**
MCC Total	700	5,676
NHSPB Total	324	1,628
Combined Total	**1,024**	**7,304**
Average Daily Census		**20.0**

Source: HiDi Market Data
CY 2023 used for NHSPB, Q1-Q2 2023 Annualized Used for MCC

As noted in discussion of Criterion (1), there are many DRGs on the LAC list that are not supported by the few specialties that are included with MCC and NHSPB. While MCC or NHSPB physicians may be associated with some of these patients when admitted to a large tertiary medical facility such as Mission Hospital, which provides a full range of service and other supporting specialists, it does not make sense for MCC or NHSPB physicians to admit these patients to the proposed NH Asheville when they have no other identified supporting specialists such as neurosurgeons, neurologists, medical cardiologists, orthopedic surgeons, or gynecologists. When these unrelated specialty DRGs are removed, the patient base is even smaller with an ADC of just 17.9, as shown in **Figure 5**.

Figure 5
MCC and NHSPB Historical 2023 Base Year Volumes
Buncombe and Henderson County Hospitals
Unrelated Specialty DRGs Removed

	Discharges	**Days**
MCC Total	624	4,938
NHSPB Total	314	1,578
Combined Total	**938**	**6,516**
Average Daily Census		**17.9**

Source: HiDi Market Data
CY 2023 used for NHSPB, Q1-Q2 2023 Annualized Used for MCC

Steps 2 and 3 calculate a 2023-2031 CAGR for the eight-county proposed service area (0.89%) and apply the CAGR to the Step One volumes to determine the total projected discharges and patient days by referring provider for NH Asheville through 2031.

MCC anticipates shifting 75% of its appropriate patients to NH Asheville. NHSPB estimates that it will shift 85% of its appropriate patients to NH Asheville. In Step 4, these percentages are applied to the provider-specific projections to calculate the projected annual discharges and patient days attributed to each referral source and an overall total. Following Novant's Steps 3 and 4 applied to clinically appropriate

patients results in far fewer projected discharges and patient days: 789 discharges and 4,094 patient days as shown in **Figure 6.** This compares to 1,036 discharges and 6,976 patient days on pages 165 and 166 of NH Asheville's application, respectively.

Figure 6

Step 3 and 4: Corrected for Clinically Appropriate Patient Types by DRG

Discharges	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
MCC Total	624	630	635	641	647	652	658	664	670
NHSPB Total	314	317	320	322	325	328	331	334	337
Combined Total	**938**	**946**	**955**	**963**	**972**	**980**	**989**	**998**	**1,007**
MCC Allocation (75%)						489	494	498	502
NHSPB Allocation (85%)						279	281	284	287
Total to NH Asheville						**768**	**775**	**782**	**789**

Patient Days	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
MCC Total	3,444	3,475	3,506	3,537	3,568	3,600	3,632	3,664	3,697
NHSPB Total	1,448	1,461	1,474	1,487	1,500	1,514	1,527	1,541	1,554
Combined Total	**4,892**	**4,936**	**4,979**	**5,024**	**5,068**	**5,114**	**5,159**	**5,205**	**5,251**
MCC Allocation (75%)						2,700	2,724	2,748	2,773
NHSPB Allocation (85%)						1,287	1,298	1,310	1,321
Total to NH Asheville						**3,987**	**4,022**	**4,058**	**4,094**

Summarizing these revised projections that take into account truly clinically appropriate patients results in acute care bed utilization of just over 43% in 2031 as shown in **Figure 7**. This level of utilization does not meet the performance standards and does not justify 26 beds.

Figure 7

Summary of Acute Care Bed Utilization for Clinically Appropriate Patients				
	2028	**2029**	**2030**	**2031**
Discharges	768	775	782	789
Patient Days	3,987	4,022	4,058	4,094
ALOS	5.19	5.19	5.19	5.19
ADC	10.92	11.02	11.12	11.22
Percent Capacity	**42.01%**	**42.38%**	**42.76%**	**43.14%**

NH Asheville's ICU Bed Projections Are Unsupported

In Step 6, NH Asheville quantifies the utilization to support four proposed ICU beds. NH Asheville takes the overstated patient definition, including clinically inappropriate patients, and uses HIDI data to identify the patients with ICU days. HIDI data only defines with an "ICU flag" whether a patient had ICU days. It does not define the actual number of ICU days. Thus, the claimed ICU days identified by Novant are all patient days for patients who had any part of their stay in the ICU. It is impossible for Novant to glean from the HIDI database how many patient days were ICU days for the patients that had an ICU stay and how many days such patients spent in medical/surgical beds as their condition improved. Moreover, it is impossible to determine Novant's projected ALOS for the ICU given the information provided in the application.

There are also mathematical errors in the table at the top of page 167. Total ICU days should reflect MCC days and NHSPB days added together for 2028-2031, but instead they only reflect NHSPB days.

Novant purportedly determines that, "with proper staffing," 13.25% of its ICU patient days can be treated in the med/surg unit. These 13.25% days are attributed to 10% of NH Asheville's leukemia and lymphoma patients, 33% of sepsis patients, and diabetic patients with neuropathy (page 167).

This statement leads to questions regarding the feasibility of these projections. It is unclear what types of patients/DRGs does NH Asheville anticipate treating in its ICU. It is also unclear what is the "proper staffing" that would allow a patient who has traditionally required care in the ICU to be treated in a med/surg bed. It is certainly unclear how can patients previously requiring ICU care be treated in a med/surg unit.

It is also unclear what physician practice is admitting sepsis patients and diabetic patients with neuropathy. Novant's projections are entirely based on actual patient utilization from MCC and NHSPB. A cancer clinic and a surgical practice do not typically care for sepsis and diabetic neuropathy patients.

The projected ADC of 3.99 in 4 beds in Year 3 (page 168) likely explains why the 13.25% adjustment was made to reduce the number of ICU patient days. Without the adjustment, its projections would have exceeded the planned ICU beds.

Novant states it used July 2022-June 2023 HIDI data for MCC because "MCC physicians stopped admitting acute leukemia and lymphoma patients to Mission Hospital for inpatient chemotherapy in the second half of 2023." Novant suggests, through MCC, that Mission Hospital is not serving these patients. Calendar Year 2023 HIDI market data does not fully support this statement. First, Mission Hospital actually discharged more leukemia patients in the second two quarters of 2023 (71 patients) than the first two quarters (67 patients), so it is clearly still admitting these patients. In addition, oncologists from practices other than MCC have also been admitting these patients. Second, it appears that MCC's admissions to Mission Hospital dropped by 11 patients (50 in Q1-2 to 39 in Q3-4), who are presumably leaving the service area. While MCC may have sent more patients out of the service area for care in Quarters 3 and 4, it continued to admit patients with leukemia to Mission Hospital in all four quarters of 2023. See **Figure 8**. MCC's decision to send 11 additional patients out of the region for care in the second half of 2023 further demonstrates that its volumes do not justify a new oncology hospital.

Figure 8

Patients from the Service Area Admitted to Mission with Acute Leukemia DRGs

	2023Q1	2023Q2	Q1-2	2023Q3	2023Q4	Q3-4	Total
Mission Hospital	28	39	67	38	33	71	138
MCC Admissions to Mission Hospital	21	29	50	25	14	39	89
Percent of Admissions from MCC			74.6%			54.9%	64.5%

Source: HIDI Analytics, CY 2023

DRGs include: 820-825, 834-842

Issues with Other Utilization Projections

Novant's utilization projections for all other hospital components are also problematic. Some of these are addressed below:

Medical Equipment (pages 169-174)

- The utilization projections for medical equipment are based on the use rates of these modalities by patients with a cancer diagnosis at Novant hospitals throughout the greater Charlotte and Winston-Salem areas. Some of these hospitals are major medical centers that care for patients of much higher acuity than NH Asheville. As a result, the use of these ratios will not result in reliable projections.

- To determine inpatient use of each modality, the use rates are applied to projected inpatient days. As outlined above, projected inpatient days are overstated. As a result, medical equipment projections will also be overstated.
- To determine outpatient use of each modality, the use rates are applied to outpatient encounters. As described below, the outpatient encounters are not calculated in a way that results in reliable projections.
- MRI is not included in this application, but Novant includes projections for MRI in Form C-2b and related assumptions. Previously in the application, NH Asheville describes using two mobile MRI units for 24/7/365 MRI availability. However, Novant only projects to provide 651 total MRI scans in Year 3 of operation, or 1.78 scans per day. Accordingly, these mobile units will be underutilized.
- The CT unit is projected to provide 2,436 CT scans in Year 3 of operation, or 6.7 scans per day. This unit will be underutilized. In addition, its inpatient scans appear to be overstated based on a combination of a flawed use rate and overstated inpatient days and outpatient encounters on which the use rate is applied.

Surgical Volume (pages 175-181)

- Inpatient surgical volume is calculated using the same basis and assumptions used to calculate inpatient days and discharges. As a result, it has the same issues outlined and discussed related to the inpatient projections above. Inpatient surgery volumes are overstated as a result.
- Novant's outpatient surgical volume is based on market data from the HIDI outpatient database. Using the same parameters and methodology it used for inpatients, Novant states that it pulled 2023 outpatient surgical procedures for MCC and NHSPB to use as a basis for projecting outpatient surgery. Again, it is impossible to assess what kinds of cases these involve.
- In addition to serving patients from MCC and NHSPB, Novant intends to shift volume from the Mission Hospital ED to its NH Asheville ED. Novant quantifies the 2023 component of Mission Hospital ED patients who received outpatient surgery through the ED and estimates that approximately 10 percent of them living in six ZIP codes near the NH Asheville hospital will shift to NH Asheville. This results in an additional 22 outpatient surgeries per year by Year 3 of operation. The annual number of "ED outpatient" surgeries for a six ZIP area seems high, as the type of surgeries warranted by an ED visit are not typically discharged immediately after surgery.

Other Hospital Services (pages 182-193)

- The projection of other hospital services is dependent on the projected inpatient days and the projected outpatient encounters. Issues with projected inpatient days which result in overstated projections are outlined in detail above. There are also issues with the applicant's methodology for projecting outpatient encounters.
- Outpatient encounters are based on Calendar Year 2023 MCC and NHSPB outpatient volume and outpatient volume shifted from Mission Hospital ED patients to NH Asheville. It is projected that 75% of MCC outpatient volume, 85% of NHSPB outpatient volume, and 10% of select Mission Hospital ED volume originating from a six-ZIP Code service area will be allocated to NH Asheville once these volumes are grown at a .89% CAGR through 2031. Again, the appropriate ICD-10 codes are not provided for these services to know what they entail.
- Very few ED visits are projected to result from patients of MCC and NHSPB. Most of the projected ED visits are patients redirected from Mission Hospital, as described above.
- Novant also includes "ED inpatients," a fourth subset of ED patients that are composed of MCC and NHSPB inpatients previously included in the inpatient days and discharges that accessed inpatient care through an ED visit. Based on 2023 data, Novant projects that 68.58% of MCC and 18% of NHSPB inpatients accessed care through the ED. Both percentages seem overstated, particularly since the leukemia and lymphoma patients referenced throughout the application are scheduled inpatients. Notably, most patients who present to the ED do not know their diagnosis or surgical needs. They are referred to or assigned to an attending physician after they present and are diagnosed. It is not

reasonable to assume that these patients, who present to the Mission Hospital ED not knowing their diagnosis or if they need surgical care, would instead choose to go to the proposed Novant ED to see the limited physicians in two specific practices – MCC or NHSPB.

- Novant projects 2,586 annual ED visits or 7.08 visits per day in Year 3 of operation. These figures indicate an underutilized ED, regardless of its size. However, NH Asheville plans to develop 10 ED bays in its proposed ED. This results in less than one visit per treatment bay each day based on Novant's projections. This is a costly project to serve seven patients per day in the ED.
- The same two-pronged methodology used to project utilization for medical equipment (see above) was used for lab, pharmacy, and therapy utilization projections and is unreliable for the same reasons.
- Therapy projections are provided as units but also indicate that a unit is equivalent to a treatment (pages 191-192). Units are used for billing in therapy services and generally represent a 15-minute increment of therapy, which is usually not the equivalent of a full treatment. It is impossible to distinguish whether these projections represent treatments or increments of treatments. In addition, it is not possible to assess whether these units/treatments were properly captured in the financial projections.

Novant's Assertions Regarding Mission Hospital to Justify Need for the Project are Inaccurate

"NH Asheville is designed to fix major problems in health care delivery in Western North Carolina identified by North Carolina Attorney General Joshua H. Stein, the press, doctors, nurse's technicians, and patients. These problems arise from Hospital Corporation of America's (HCA) management decisions since acquiring the Mission Health System (Mission) in 2019, and from Mission's dominance of hospital services in Western North Carolina." Application, Page 1

Novant has leveled many accusations at Mission Hospital throughout its CON application and has largely based its application on reciting the accusations made by Attorney General Josh Stein regarding cancer care at Mission Hospital. Novant first references these accusations in its Executive Summary and re-references them throughout the body of the application. It appears that Novant has assumed all allegations and accusations within Mr. Stein's letter and from other sources to be based on proven fact despite the fact that the related litigation is still pending, with Mission having admitted no such facts and no court or jury having made any such findings of fact. Novant provided little to no analysis in its application to demonstrate that its assumptions regarding Mission Hospital are true.

In fact, the statements Novant makes about Mission Hospital are inaccurate. It is important to note:

- *HCA Did Not take 20 Oncology Beds Out of Service (See Novant Executive Summary page 4).*

Mission Hospital's licensed oncology beds have only increased since 2019 when HCA acquired Mission Hospital. This information is available publicly in LRAs. In addition, except for 2019 when 30 out of 31 oncology beds were operational, all licensed oncology beds have also been operational since 2019. Novant's statements regarding Mission's oncology beds are simply unfounded as shown in **Figure 9**.

Figure 9
Mission Hospital Licensed Oncology Beds by Year

	2016	2017	2018	2019	2020	2021	2022	2023	2024
Oncology Beds	29	29	29	31	31	44	44	44	44

Source: LRAs

In addition, Novant states and implies that Mission Hospital does not keep all beds in operation due to staffing and other issues. This is an inaccurate and unsupported assertion. Mission Hospital has been operating at full capacity for years and was recently granted 73 additional acute care beds to meet the urgent

need for additional beds. Any operational issues that Mission Hospital may have experienced were related to its bed shortage and not to the factors indicated by Novant.

While Novant's claims regarding Mission's oncology beds are unfounded, it should be noted that Novant Health does not propose to include licensed oncology beds in its application. All beds are categorized and will be licensed as general medical/surgical beds.

- *Mission Hospital Continues to Provide Services to Leukemia and Lymphoma Patients (Novant Executive Summary pages 1-2)*

Mission Hospital has not discontinued these services and continues to provide these services today.

It is clear that Mission Hospital has consistently provided services to leukemia patients through calendar year 2023. Mission's acute leukemia discharges increased from the first half of 2023 (67) to the second half of 2023 (71). While MCC's referred discharges may have decreased from about 75% of Mission's leukemia patients to about 55%, Mission's volume overall has increased. Please see **Figure 10**.

Figure 10
Patients from the Service Area Admitted to Mission with Acute Leukemia DRGs

	2023Q1	2023Q2	Q1-2	2023Q3	2023Q4	Q3-4	Total
Mission Hospital	28	39	67	38	33	71	138
MCC Admissions to Mission Hospital	21	29	50	25	14	39	89
Percent of Admissions from MCC			74.6%			54.9%	64.5%

Source: HIDI Analytics, CY 2023
DRGs include: 820-825, 834-842

Any claim questioning the availability or provision of comprehensive cancer services at Mission Hospital is inaccurate.

- *Mission Hospital is a Sarah Cannon Cancer Network Location.*

Mission Hospital is owned by HCA Healthcare. Sarah Cannon Cancer Network ("SCC") is the Cancer Institute of HCA. Mission's cancer services are 100% part of the Sarah Cannon network and utilize SCC best practices. Mission Hospital is listed on the SCC website as of the date of filing these comments.

- *Mission Hospital employs a medical oncologist.*

Mission Hospital has an employed medical oncologist focused on breast cancer. That said, Mission Hospital has multiple medical oncologists that are active on its staff even if not employed by Mission. Physician employment by the hospital is not a necessity for any hospital to offer subspecialty or comprehensive care. In fact, all MCC physicians are still active members of Mission's medical staff, though they are not employed by Mission.

In addition, Mission Hospital has numerous other oncologists and oncology specialists on its medical staff. **All members of MCC and NHSPB are on Mission Hospital's medical staff and actively admitting patients.** As shown in **Figure 11**, Mission's other oncology specialists include numerous physicians in a wide range of specialties. This is not an all-inclusive list of all medical staff members that participate in the multidisciplinary care of Mission's cancer patients, which includes physicians consulting in additional areas such as cardiology, pathology, radiology, nurse navigators, advance practice providers, physician assistants, and physical therapist all of whom support a full continuum of cancer related diagnosis and treatment. By contrast, NH Asheville admits it does not know what other physician specialties will be on its medical staff.

Figure 11

Mission Hospital Cancer Providers on Staff

Name	Specialty	Practice
Michele LeBlanc, MD	Breast Surgery, Ob-Gyn	Western Carolina Women's Specialty Center
John Whitfield, MD	Colon and Rectal Surgery	Mission Surgery
Colin Bird, MD	Colon and Rectal Surgery	Novant Health Surgical Partners - Biltmore
Melissa Zoumberos, MD	Colon and Rectal Surgery	Novant Health Surgical Partners - Biltmore
Paul Davis, MD	ENT, Head & Neck Surgery	Head & Neck Specialists - Western North Carolina
Stephen Dennis, MD	ENT, Head & Neck Surgery	Head & Neck Specialists - Western North Carolina
Craig Cender, MD	Gastroenterology	Digestive Health Partners
Andrew Dukowicz, MD	Gastroenterology	Digestive Health Partners
Jessica Fisher, MD	Gastroenterology	Digestive Health Partners
Brian Garvin, MD	Gastroenterology	Digestive Health Partners
William Harlan, MD	Gastroenterology	Digestive Health Partners
Michael Heacock, MD	Gastroenterology	Digestive Health Partners
Daniel Hogan, MD	Gastroenterology	Digestive Health Partners
David May, MD	Gastroenterology	Digestive Health Partners
Angela Meyer, MD	Gastroenterology	Digestive Health Partners
Brendon O'Connell, MD	Gastroenterology	Digestive Health Partners
Rodney Perez, MD	Gastroenterology	Digestive Health Partners
Charles Schrode, MD	Gastroenterology	Digestive Health Partners
Evan Tiderington, MD	Gastroenterology	Digestive Health Partners
Tom Whitlock, MD	Gastroenterology	Digestive Health Partners
Adam Zivony, MD	Gastroenterology	Digestive Health Partners
Cameron Coker, MD	General Surgery - Breast Surgery	Hope Women's Cancer Center
Amy Alexander, MD	Gynecology Oncology	Hope Women's Cancer Center
Ashley Case, MD	Gynecology Oncology	Hope Women's Cancer Center
Cameron Blair Harkness, MD	Gynecology Oncology	Hope Women's Cancer Center
Timothy Vanderkwaak, MD	Gynecology Oncology	Hope Women's Cancer Center
Benjamin Motz, MD	Hepatobiliary Surgery	Mission Surgery
Jesse Sulzer, MD	Hepatobiliary Surgery	Mission Surgery
Joshua Baru, MD	Hospice and Palliative Care	Messino Cancer Centers
Raymond Barfield, MD, PhD	Hospice and Palliative Care	Mission Palliative Care
David Farley, MD	Hospice and Palliative Care	Mission Palliative Care
Caroline Knox, MD	Hospice and Palliative Care	Mission Palliative Care
Haley Neal, MD	Hospice and Palliative Care	Mission Palliative Care
Christopher Patterson, MD	Hospice and Palliative Care	Mission Palliative Care
Casey Sharpe, MD	Hospice and Palliative Care	Mission Palliative Care
Dennis Campbell, MD	Neurosurgery	Carolina Spine and Neurosurgery
Wesley Fowler, MD	Neurosurgery	Carolina Spine and Neurosurgery
Richard Lytle, MD	Neurosurgery	Carolina Spine and Neurosurgery
Eric Rhoton, MD	Neurosurgery	Carolina Spine and Neurosurgery
Peter Steenland, MD	Neurosurgery	Carolina Spine and Neurosurgery
Robert Oxford MD	Neurosurgery	Carolina Spine and Neurosurgery
Coridon Quinn, MD	Neurosurgery	Carolina Spine and Neurosurgery
Brent Skiver, DO	Oncology-Hematology	Messino Cancer Centers
Jessica-Lyn Masterson	Oncology-Hematology	Hope Women's Cancer Center
Treavor Austin, MD	Oncology-Hematology	Messino Cancer Centers
Andrew Beardsley, MD	Oncology-Hematology	Messino Cancer Centers
Charles Bryan, MD	Oncology-Hematology	Messino Cancer Centers
Christopher Chay, MD	Oncology-Hematology	Messino Cancer Centers
Shantae Lucas, MD	Oncology-Hematology	Messino Cancer Centers
Erik Luk, MD	Oncology-Hematology	Messino Cancer Centers
Emily Miller, MD	Oncology-Hematology	Messino Cancer Centers
Martin Palmeri, MD	Oncology-Hematology	Messino Cancer Centers
Wieslawa Pekal, MD	Oncology-Hematology	Messino Cancer Centers
Rachel Raab, MD	Oncology-Hematology	Messino Cancer Centers
Mohan Thakuri, MD	Oncology-Hematology	Messino Cancer Centers
Sean Warsch, MD	Oncology-Hematology	Messino Cancer Centers
Donald Gajewski, MD	Orthopedic Oncology	Mission Orthopedic Trauma Services
Krystal Bottom, MD	Pediatric Heme-Onc	Mission Pediatric Hematology/Oncology
Katherine Harris, MD	Pediatric Heme-Onc	Mission Pediatric Hematology/Oncology
Douglas Scothron, MD	Pediatric Heme-Onc	Mission Pediatric Hematology/Oncology
Paul Tenzel, MD	Plastic Surgery, Breast Reconstruction	Mission Cancer Specialists
Sarah Sher, MD	Plastic Surgery, Breast Reconstruction	Mission Cancer Specialists
Ryan Brown, MD	Pulmonary Disease	Asheville Pulmonary & Critical Care Associates
Allen Elster, MD	Pulmonary Disease	Asheville Pulmonary & Critical Care Associates
Timothy Heacock, MD	Pulmonary Disease	Asheville Pulmonary & Critical Care Associates
Patton Thompson, MD	Pulmonary Disease	Asheville Pulmonary & Critical Care Associates
Quinten Black, MD	Radiation Oncology	GenesisCare
Jeffrey Roberts, MD	Radiation Oncology	GenesisCare
Daniel Baseman, MD	Radiation Oncology	GenesisCare
Joseph Kelley, MD	Radiation Oncology	GenesisCare
James Broughman, MD	Radiation Oncology	Mountain Radiation Oncology
Kellie Condra, MD	Radiation Oncology	Mountain Radiation Oncology
Matthew Hull, MD	Radiation Oncology	Mountain Radiation Oncology
Eric Kuehn, MD	Radiation Oncology	Mountain Radiation Oncology
William McCollough, MD	Radiation Oncology	Mountain Radiation Oncology
Sesalie Smathers, MD	Radiation Oncology	Mountain Radiation Oncology
Paul Ahearne, MD	Surgical Oncology	Novant Health Surgical Partners - Biltmore
Benjamin Deschner, MD	Surgical Oncology	Novant Health Surgical Partners - Biltmore
Oliver Binns, MD	Thoracic Surgery	Asheville Heart
Jesse Madden, MD	Thoracic Surgery	Asheville Heart
John Burns	Urologic Oncology	Mission Urology

Novant Health's claims to be a more cost-effective alternative for patients and payors are unfounded

Novant uses the same RAND data throughout the application (pages EC4, EC5, 28, 29, 82, 83, 146, 147) to show rate comparisons for inpatient and outpatient services for the three applicants, claiming that it is the most cost effective. However, it does not provide sufficient information about this data to determine if these are "apples-to-apples comparisons." A recent study showed that Novant's claims of cost-effective healthcare may not apply to its provision of cancer care. See **Attachment B**. Novant Health was recently identified as raising the costs of cancer drugs obtained through the 340B program, which requires drug manufacturers participating in Medicaid to sell discounted drugs to eligible entities including non-profit hospitals that provide charity care. The intent of the program is to increase access to these drugs for uninsured and low-income patients. The study detailed 340B cancer drugs provided by New Hanover Regional Medical Center, acquired by Novant in 2021, that were sold to patients 70% above average sale price. As a systemwide hospital network, Novant had the fifth highest average oncology drug markups among 15 listed providers to the State Health Plan. A Brown University healthcare policy expert who worked on the recent study said Novant Health had a 260% profit margin on cancer drugs acquired through the discounted program. This information is vital to the consideration of Novant's application as Novant proposes a cancer-focused hospital.

NH Asheville Contributes to the Underlying Need Identified for Acute Care Beds

Novant's proposed project largely serves as an underutilized Freestanding ED attached to a small, underutilized acute care hospital. As an ED, Novant Asheville will see patients of all acuities, illnesses, and injuries. Some of these patients will be discharged from the ED; some low-acuity patients will be admitted; and others will be transferred out for higher level inpatient care. Novant states on page 37 of its application:

> NH Asheville will have a full-service emergency department with ten treatment rooms on the first floor, near the imaging and laboratory services. The emergency department will be staffed 24/7 by emergency physicians, nurses, and other clinicians. The emergency department is not limited to treating cancer patients or patients suitable for inpatient care at NH Asheville. The medical staff, onsite and through telemedicine, can stabilize patients with almost any diagnosis before admitting them for further treatment at NH Asheville, transferring them to another hospital offering a higher level of care, or discharging them home.

Those patients who are transferred to another hospital for a higher level of care will likely be transferred to Mission Hospital, given its location and capabilities. As shown in the 2024 SMFP, the need for the 26 acute care beds under review was generated by the historical utilization of Mission. In May 2024, Mission Hospital was granted emergency use of 73 acute care beds due to its operating capacity. This is just one more indicator that these 26 beds are not best used in another community hospital; they are needed to care for the thousands of patients that are transferred each year from lower acuity hospitals throughout western North Carolina to Mission Hospital for high-acuity care.

Novant's proposed project will simply add another ED and a low-acuity acute care provider that will transfer its higher acuity patients to Mission, which ultimately needs the 26 beds to serve these transferred patients. Novant is not proposing to use these beds to meet a demonstrated need of the service area. Instead, it focuses on providing low-acuity inpatient cancer services (even though inpatient cancer services are generally not low-acuity services) to the patients of two specific physician practices while proposing no ancillary services or equipment related to specialty cancer care as part of its "cancer-focused" project.

For the reasons outlined above, Novant is not conforming with Criterion (3)

Criterion (3a) Novant and OSCA Have Not Demonstrated that the Expensive Replacement and Relocation of an ASF OR to a Hospital-Based OR Meets the Needs of the Population.

For the reasons outlined in detail in Criterion (1) above, the proposed transfer of the freestanding outpatient operating room from OSCA to NH Asheville for hospital-based and inpatient use will not meet the needs of the population presently served by this dedicated freestanding outpatient OR. In fact, it will eliminate a lower cost, higher efficiency option for the service area and result in the need for additional ambulatory surgical facility operating rooms.

History of OSCA's OR

- OSCA obtained approval for two additional ORs to provide a service that was quantitatively shown to be needed in the community in a dedicated freestanding ASF setting.
- This CON was filed pursuant to a determination of need in the 2018 SMFP.
- OSCA constructed an entirely new ASF containing the OR proposed to be transferred, which opened in approximately September 2021.
- Novant now proposes to transfer the ambulatory OR to be used in a completely different capacity as a shared use, hospital-based OR.
- OSCA, a new facility with five ambulatory operating rooms, has not even been in operation for three years. CON applications require three years of projections for review. This transfer impacts all assumptions on which the approval of this application was based.

Inappropriate Use of ORs and Procedure Rooms

- Novant states that OSCA can either backfill the transferred OR with another licensed OR once the CON requirements sunset for ASFs in counties with populations over 125,000 or it can use the space as a procedure room to perform surgeries.
- NH Asheville proposes three procedure rooms in addition to the transferred OR to be used for surgical procedures. But procedure rooms are not considered by Operating Room Performance Standards required.

The Transferred OR Will Not Meet the Needs of Patients for Low Cost ASF Services

The ASF setting is generally accepted to differ from the hospital-based surgical setting in the following ways:

- Higher efficiency in terms of cases and OR turnover
- Lower out of pocket costs for patients than outpatient surgery in an acute care hospital
- Easier access and convenience than a hospital setting

In fact, OSCA made these same assertions in its 2018 application to the Department to develop a new facility by adding two outpatient ORs to its existing three operating rooms (for a total of five freestanding outpatient multi-specialty ORs). Specifically, its application contained the following comments:

Changes in Reimbursement, Cost Savings and Patient Choice

The list of surgical procedures provided at ambulatory surgical centers that are reimbursable under Medicare, Medicaid and commercial insurance has expanded in recent years. Freestanding ambulatory surgery centers provide advantages to patients and payors including:

- **Lower cost of care due to lower ASC reimbursement**
- **Convenient sites of care including superior convenience, access and efficiency**
- **Physician alignment through partnering with the ASC and medical staff**

Source: Application for Asheville SurgCare, ID No. B-11514-18, p34

As seen in the following table, a comparison of some of the most frequently performed outpatient orthopedic surgical procedures shows that ambulatory surgery centers have lower charges as compared to hospitals.

Comparison of BCBS Estimated Treatment Costs	Orthopaedic Surgery Center of Asheville	Park Ridge Hospital	Margaret R. Pardee Memorial Hospital
Counties	Buncombe	Henderson	Henderson
Carpal Tunnel	$2,207	$5,518	$5,457
Knee Arthroscopy with Cartilage Repair	$3,843	$9,846	$9,312

The relocation and replacement of the three existing operating rooms at OSCA to the proposed Asheville SurgCare will enable patients to continue to have access to cost effective orthopedic, spine and podiatry surgery. The proposed two additional operating rooms that originate from the 2018 SMFP need determination will be used in combination with the three relocated ORs to serve increased numbers of orthopedic, podiatric and pain management patients as well as other surgical specialties that include ophthalmology, plastic surgery, urology and pain management surgery.

Source: Application for Asheville SurgCare, ID No. B-11514-18, p36

There are only two ASFs in the Buncombe/Madison/Yancey service area, OSCA and an eye surgery center, with a combined total of 6 ORs.[2] Thus, service area residents already have very limited access to outpatient services in an ASF environment. Converting this outpatient ORs to hospital-based and shared inpatient/outpatient status will not meet the needs of service area residents and is inconsistent with OSCA's representation to the Agency when this OR application was approved.

The Transferred OR will Not Increase Access to Outpatient Surgical Services

[2] The OR service area definition in the SMFP does not include Graham County.

The OR proposed for transfer was determined to be needed for the Buncombe/Madison/Yancey OR service area in its original review. Moving this OR to southern Buncombe County will make it less accessible for Madison and Yancey County residents. OSCA is located north of the proposed hospital, and patients from Madison and Yancey Counties will have to travel further south to the hospital-based OR. The proposed OR transfer will not meet the needs of the service area residents and the intended purpose for which it was approved and just recently constructed.

Novant should also be found nonconforming with Criterion (3a) because this criterion requires that an applicant who is proposing the reduction or elimination of a service, **including the relocation of a facility or service,** demonstrate that the needs of the population presently served by that reduction, elimination, or relocation of a facility or service, will be met by the proposed relocation or by alternative arrangements. In response, Novant has provided no explanation of how the patients currently served at the OSCA will have ongoing access to outpatient surgeries that are currently being performed in the relocated OR. OSCA is not listed as a partner in this application. Its physicians have not been identified as potential referral sources or among those joining the medical staff. The OSCA ASF's operating rooms, as documented herein, are already operating beyond capacity. Based on OSCA's own representations in its 2018 ASF OR CON application, an outpatient OR and a hospital-based shared OR are not the same thing.

Criterion (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.

Novant fails to demonstrate that its project is either the least costly or most effective alternative. From a cost standpoint, adding beds to an existing facility is the more cost-effective option as it only requires construction and incremental costs associated with the addition. Novant instead proposes a small, 26-bed hospital with the highest cost per bed of any hospital proposed in the last five years. See **Figure 12**. While Novant labels its proposed hospital as a specialized cancer or cancer/surgical hospital, it fails to include any equipment or service components beyond those found in a typical community hospital, yet it has the costs associated with a larger, higher-acuity provider.

Figure 12
Comparison of Cost per Bed for Recent Acute Care Hospital Projects

Approval Year	Hospital Name	County	# of Acute Care Beds	# of Obs Beds	# of ED Bays	Cost per Bed	Cost per Bed w/ Obs Beds
2024	**Novant Health Asheville Medical Center**	**Buncombe**	**26**	**6**	**10**	**$8,960,590**	**$7,280,479**
2024	**AdventHealth Asheville**	**Buncombe**	**93**	**18**	**12**	**$3,660,897**	**$3,067,238**
2024	UNC Hospitals-RTP	Durham	112	16	28	$7,746,034	$6,777,779
2023	AHWFB - Greensboro	Guilford	36	12	20	$6,847,250	$5,135,438
2023	Atrium Health Lake Norman*	Mecklenburg	30	8	8	$7,446,327	$5,878,679
2023	WakeMed Garner Hospital	Wake	31	14	25	$6,461,290	$4,451,111
2022	Atrium Health Harrisburg	Cabarrus	24	NA	12	$3,575,917	$3,575,917
2022	**AdventHealth Asheville**	**Buncombe**	**67**	**18**	**12**	**$3,524,254**	**$2,777,941**
2022	UNC Hospitals-RTP	Durham	74	20	20	$6,705,604	$5,278,880
2021	UNC Hospitals-RTP	Durham	40	10	12	$5,422,713	$4,338,171
2021	Atrium Health Steele Creek	Mecklenburg	26	NA	NA	$2,067,948	$2,067,948
2021	Duke Green Level Hospital	Wake	40	12	15	$5,875,000	$4,519,231
2021	Atrium Health Union West^	Union	40	4	10	$3,651,570	$3,319,609
2021	Novant Health Steele Creek	Mecklenburg	32	16	16	$5,287,774	$3,525,183
NA	New Hanover Regional - Scott Hills"	New Hanover	66	6	12	$3,181,004	$2,915,920
2020	CaroMont Regional - Belmont	Gaston	54	12	16	$3,625,848	$2,966,603
2019	Novant Health Ballantyne	Mecklenburg	36	12	15	$3,853,834	$2,890,375

Source: CON Applications and Agency Findings

In addition to the capital construction and equipment costs associated with new construction, Novant's project involves significant operating costs including the clinical, administrative, support staff, services, and overhead required to support an entirely new hospital operation. The CON Statute sets forth a clear mandate to control costs. Of the three applicants, Novant's proposal is by far the costliest alternative.

In addition to being costly, Novant's application does not represent the most effective alternative. As described previously, Novant proposes an acute care hospital that focuses on cancer but provides no specific cancer services or equipment, such as radiation therapy or PET/CT. On page 34 of the application, Novant states, "Patients at NH Asheville Medical Center will have access to the full spectrum of services provided by the NH Cancer Institute. This includes the latest in cancer treatments, access to clinical trials, and comprehensive support resources. As explained elsewhere in this application, the quality of cancer care at existing hospitals is a problem in Western North Carolina, with many residents travelling significant distances outside the service area to receive cancer care. This application addresses this problem directly." NH Asheville will not provide any high-level cancer care. For its patients to receive these services from a Novant provider, they will have to access another NH Cancer Institute hospital. There are no NH Cancer Institute hospitals in western North Carolina. These patients will still have to leave western North Carolina for advanced treatment from Novant in Charlotte or Winston-Salem. However, advanced cancer services are available at Mission Hospital. Therefore, most cancer patients do not have to leave western North Carolina for care.

For these reasons and the associated discussions regarding Criteria (1), (3), (5), (12), and (20), Novant cannot be found conforming with Criterion (4).

Criterion (5) Financial Feasibility

Capital Costs

Shown in **Figure 12** and discussed in relation to Criterion (4), Novant has the highest cost per bed of any hospital proposed in the last five years, though it offers no unique or distinct features, equipment, or services that support its costs being higher than other proposed hospitals of similar size and offerings.

Projected Utilization

As discussed in detail in Criterion (3), Novant's projected utilization is based on a flawed methodology that overstates almost all service components for the proposed facility. As a result, Novant's financial projections are unsupported. There is no way to verify that the proposed project is financially feasible based on Novant's projected utilization as it is entirely based on unidentified and undocumented services.

More significantly, Novant has projected a Year 3 net income of just over $1 million. This leaves little room for the significant errors in utilization projections that were well-documented in the Criterion (3) discussion above. This is compounded by the deficit in inpatient net income. Below is the projected net income for inpatient services presented in the application. In Years 2 and 3, inpatient services are projected to lose more than $7 million per year. As these figures reflect a 73% occupancy level, there is not room for significant growth in utilization, even if the growth factor used was higher. Inpatient services are unlikely to become profitable under these circumstances. As shown in response to Criterion (3), the inpatient utilization is likely much lower than projected, making the inpatient net loss shown below a conservative estimate. Even if Novant meets its inpatient projections, any underestimation of its projected surgical and outpatient utilization or other unforeseen issues will result in the project operating in the negative in the long term.

Form F.2 Revenues and Net Income Criterion (5) NH Asheville- Inpatient	Interim Project Year From: 12/01/2028 To: 12/31/2028	1st Full FY From: 01/01/2029 To: 12/31/2029	2nd Full FY From: 01/01/2030 To: 12/31/2030	3rd Full FY From: 01/01/2031 To: 12/31/2031
Patient Services Gross Revenue				
Self Pay	$166,935	$2,083,783	$2,163,164	$2,249,775
Insurance *	$2,080,723	$25,972,873	$26,962,291	$28,041,834
Medicare *	$4,137,598	$51,648,062	$53,615,559	$55,762,271
Medicaid *	$715,435	$8,930,501	$9,270,702	$9,641,891
Other (Other Govt, Institutional, Tricare, Workers	$226,554	$2,827,992	$2,935,722	$3,053,266
Total Patient Services Gross Revenue	$7,327,245	$91,463,211	$94,947,438	$98,749,037
Other Revenue (1)				
Total Gross Revenue (2)	$7,327,245	$91,463,211	$94,947,438	$98,749,037
Adjustments to Revenue				
Charity Care	$166,935	$2,083,783	$2,163,164	$2,249,775
Bad Debt	$87,194	$1,088,412	$1,129,875	$1,175,114
Contractual Adjustments	$6,039,073	$65,831,045	$65,033,401	$67,637,273
Total Adjustments to Revenue	$6,293,202	$69,003,241	$68,326,439	$71,062,161
Total Net Revenue (3)	$1,034,043	$22,459,970	$26,620,998	$27,686,876
Total Operating Costs (from Form F.3)	$2,636,684	$32,386,020	$33,912,914	$34,882,999
Net Income (4)	($1,602,641)	($9,926,050)	($7,291,916)	($7,196,123)

Payor Mix

Like its utilization assumptions, Novant's payor mix is inaccurate. For inpatient care, Novant bases its payor mix on the same set of historical patients in which it based its inpatient utilization, i.e., patients of MCC and NHSPB. Rather than evaluating the payor mix for the actual service area, it assumes that its payor mix will be identical to that of two referring practices because these are the patients it intends to serve. This further solidifies that Novant does not intend to meet the needs of the service area as a whole with its proposed hospital, but to serve two practices with which it has affiliated. See Application page 205.

Novant's payor mix for outpatient surgical services and other outpatient services is unclear. As shown below, Novant bases the payor mix for these services, at least in part, on patients it expects to shift from the Mission Hospital ED to the NH Asheville ED. This is unrealistic, as outpatient surgical patients are typically scheduled and elective and few are generated through the ED. These ED patients would not reflect the expected payor mix for outpatient surgery and general outpatient services.

> other area hospitals would be served at NH Asheville. The payor mix for outpatient surgical services and other (non-surgical) outpatient services also includes the payor mix of outpatients expected to shift from the Mission emergency department to NH Asheville's emergency department. The details of which patients will shift are in the assumptions for Form C.4b in Section Q.

Source: Application for Novant Health Asheville Medical Center, ID --24, Assumptions to F.2b, page 205

The total facility payor mix combines the individual payor mix projections to result in an incohesive projection that is not tied to the overall community it should be serving. As a result, these projections are unfounded.

Operating Costs

Novant's high operating costs impact the financial feasibility of the project. Novant's operating costs average approximately $50 million annually in the first three years of operation and are projected to grow each year. These projections are unusually high for a hospital that only has 26 beds and provides community hospital services. See related discussion regarding staffing under Criterion (7).

For these reasons, Novant should be found non-conforming with Criterion (5).

Criterion (6) Unnecessary Duplication

On page 113 of its application, Novant asserts that, because the SMFP shows a need for 26 acute care beds to serve the Buncombe, Graham, Madison, and Yancey Counties service area, a proposal to utilize these beds cannot be an unnecessary duplication of "assets." See below. This statement is both simplistic and inaccurate. An applicant must show that the intent and use of the beds does not unnecessarily duplicate existing providers. In other words, an applicant must show that there is a need for another provider of the same or similar services in the service area. It does not mean that any use of these 26 acute care beds is needed simply because there is a need determination in the SMFP.

> The 2024 SMFP shows a need for 26 additional acute care beds in the Buncombe/Graham/Madison/Yancey service area. To meet the need, Novant Health is submitting this CON application. Therefore, the acute care beds proposed in this application are part of the needed assets and cannot be an unnecessary duplication of assets.
>
> This project will not result in unnecessary duplication of existing or approved services or facilities because this proposal is consistent with the need determination. This application adequately demonstrates the need to develop the proposed beds at the proposed location in Buncombe County, based on the number of projected patients to be served.

In Novant's case, it is difficult to determine the purpose, patients, and service lines for the proposed hospital. Much of the application identifies the hospital as cancer focused. In some places, the hospital is described as cancer and surgery focused. However, Novant also states that its proposed hospital has the capability to serve the spectrum of Limited Acute Care MS-DRGs that are shown in **Attachment A,** which span well beyond oncology and surgery diagnoses and treatments.

If Novant Health Asheville is truly intended to be a cancer focused hospital or a cancer/surgery focused hospital, the proposed project is an unnecessary duplication of services for several reasons. First, it fails to provide any specialized cancer services. Given its capabilities and equipment, it can only provide general acute care to cancer patients. Novant does not describe any specialized inpatient programs or ancillary services for cancer patients. Any specialized cancer services from PET/CT diagnostics to radiation therapy must be referred to another provider. Second, it proposes to take a licensed OR from the only multi-specialty ASF in Buncombe County, which currently shows a need for 1.41 additional ORs in the draft 2025 SMFP and use it as a shared OR that will bill as a hospital-based provider. Third, and most importantly, as a cancer and surgical focused hospital, it only proposes to serve the patients of two physician practices. All application assumptions including the service area, projected utilization, and payor mix are built upon this fact. A general acute care hospital which provides no specialized services and takes an ASF OR to serve only patients originating from two physician practices would be a duplication of services when there is already any existing acute care provider (Mission), an approved acute care provider (AdventHealth), and an ASF in Buncombe County to provide these services. In addition, Novant proposes to construct its hospital at the Henderson County line, just miles from two other acute care providers in Hendersonville as well as 9.5 miles from Mission Hospital in Buncombe County.

While NH Asheville's limited medical staff might be specialized, that doesn't mean their service offerings are unique. NH Asheville does not have the proposed services or equipment to offer anything outside the capabilities of a small community hospital. NH Asheville's intent to serve counties well outside of the SMFP service area that already have local hospitals with abundant capacity for additional patients (See Application pages 112 and 113) demonstrates that this project is an unnecessary duplication of existing services. In addition, Novant is proposing to spend $250 million dollars to offer services already offered

by Mission, AdventHealth Hendersonville, and UNC Health Pardee Medical Center, all of which are located less than 15 miles from the proposed hospital.

For these reasons and those referenced in the associated discussions of Criteria (1), (3), (4), and (18a), Novant should be found non-conforming with Criterion (6).

Criterion (7) Availability of Resources.

The healthcare industry is facing a considerable staffing shortage in the wake of COVID. The proposed project will place further demands on the availability of staff in the planning area and the region, including by competing for staff with existing hospitals in Henderson and Buncombe Counties. The development of a new duplicative hospital will require over 223 FTEs by the third year of operation as proposed by Novant. This includes over 79 nursing staff and over 90 technical and therapy staff, all of whom are in high demand and experiencing shortages. See Section Q, Form H. Of the three applicants, Novant projects the highest volume of staffing by far with 223.5 total Year 3 staff. Novant does not clearly document how it will obtain such high levels of staffing.

Criterion (12) Cost and Design

Construction and Design

Novant does not demonstrate that its construction, design, and site choices represent the most reasonable alternative. As discussed previously and shown in **Figure 12**, the cost per bed is among the highest of all new hospitals reviewed in the last five years. However, cost is not the only factor. The proposed hospital is oversized for the number of beds proposed. Of all new community hospitals reviewed in the last five years, it has the second highest square footage per bed with 6,207 square feet per bed. See **Figure 13** below.

Figure 13
Comparison of Square Footage per Bed for Recent Small Hospital Applicants

Approval Year	Hospital Name	County	# of Acute Care Beds	Square Footage	Square Feet per Bed
2024	**Novant Health Asheville Medical Center**	**Buncombe**	**26**	**161,402**	**6,208**
2024	**AdventHealth Asheville**	**Buncombe**	**93**	**270,204**	**2,905**
2024	UNC Hospitals-RTP	Durham	112	595,840	**5,320**
2023	AHWFB - Greensboro	Guilford	36	158,736	**4,409**
2023	Atrium Health Lake Norman*	Mecklenburg	30	160,000	**5,333**
2023	WakeMed Garner Hospital	Wake	31	NA	
2022	Atrium Health Harrisburg	Cabarrus	24	53,851	**2,244**
2022	**AdventHealth Asheville**	**Buncombe**	**67**	**226,910**	**3,387**
2022	UNC Hospitals-RTP	Durham	74	441,418	**5,965**
2021	UNC Hospitals-RTP	Durham	40	189,838	**4,746**
2021	Atrium Health Steele Creek	Mecklenburg	26	54,436	**2,094**
2021	Duke Green Level Hospital	Wake	40	298,960	**7,474**
2021	Atrium Health Union West^	Union	40	150,000	**3,750**
2021	Novant Health Steele Creek	Mecklenburg	32	185,992	**5,812**
NA	New Hanover Regional - Scott Hills"	New Hanover	66	197,891	**2,998**
2020	CaroMont Regional - Belmont	Gaston	54	222,040	**4,112**
2019	Novant Health Ballantyne	Mecklenburg	36	161,988	**4,500**

Source: CON Applications and Agency Findings

As shown on page 190 of its application and below, Novant projects 7.08 ED visits per day in Year 3 of operation, yet it proposes to construct a 10-bay ED. This results in less than one visit per treatment bay each day in Novant's third year of operation. Novant provides no explanation to justify a 10-bed ED to care for seven patients per day.

NH Asheville Projected ED Visits

	2028	2029	2030	2031
Total ED Visits	210	2,540	2,563	2,586
Visits Per Day	6.77	6.96	7.02	7.08

Source: Step 10

Novant also includes two mobile MRI pads in its design so that it can offer 24/7/365 MRI services utilizing two rotating mobile MRI units. However, Form C.2b shows that Novant projects to provide 651 MRI scans annually in Year 3 of operation – less than two scans per day. Again, this level of utilization does not justify the level of construction cost and operating expense that is required for the provision of this service.

Site Issues

The proposed location is composed of three adjacent sites, two of which are zoned residential and will require a special use permit for development of the proposed project. Novant has disclosed that it will have to go through the zoning/special use process for this part of its parcel. This may result in issues that have not yet been considered related to its proposed project site and related approvals that will be necessary through Buncombe County.

Novant does not provide the required documentation regarding the availability of utilities. It identifies the companies which provide utility services in the area but provides no documentation from local providers that there are utilities sufficient for a new hospital at the proposed site. Again, the cost of bringing utilities to this site may not have been considered as there is no documentation to show their availability.

For these reasons, the project cannot be found conforming with Criterion (12).

Criterion (13) Medically Underserved Population

Novant claims it will serve medically underserved populations in its application, but its patient origin and payor mix projections indicate otherwise. As discussed previously, both patient origin and payor mix mirror that of MCC and NHSPB. If these assumptions are true, then it indicates that Novant did not consider the medically underserved population and only considered the two practices it proposes to serve with this project. See Criterion (5).

The 2024 SMFP defines the bed need for this project to originate from Buncombe, Graham, Madison, and Yancey Counties. However, Graham, Madison, and Yancey Counties only make up 5.7% of NH Asheville's total proposed patients, while its four non-SMFP service area counties and other in-migration make up 29.12% of total patients. These three counties are included in the SMFP multi-county service area because they are rural in population. Graham, Madison, and Yancey Counties embody the definition of medically underserved. NH Asheville's proposal will not improve access to medically underserved populations and, as a result, it cannot be found conforming with Criterion (13).

Criterion (18a) Novant's Project will Not be Cost Effective, Offer Quality Care, Increase Access, or Improve Competition

As discussed in detail above regarding Criteria (1), (3), (4), (5), (6), (7), (8), (12), (13), and below regarding Criterion (20), Novant does not propose a cost-effective project. The proposed new hospital does not represent the most cost-effective option to develop 26 beds when capital or operating costs are considered. Moreover, these costs are unreasonable given Novant has also failed to demonstrate the need for the project.

On page 145, Novant attempts to define itself as a different type of provider than Mission Hospital or AdventHealth, based on its claim to be a cancer-focused hospital (see excerpt below). However, its MSDRGs presented in **Attachment A** demonstrate that its intent is actually just to provide services that are in line with that of a general community hospital. There are already two acute care facilities, either approved or existing, in Buncombe County and two more acute care facilities in Henderson County that are less than 15 miles from Novant's proposed location. Each of these facilities has the capability to treat the patients Novant proposes to treat.

> Because NH Asheville will be a cancer-focused hospital, it will not unnecessarily duplicate existing services. As discussed in detail in Section C, Question 4, Mission Hospital's ability to provide comprehensive cancer care has been questioned by the North Carolina Attorney General, by local residents, and by local press. Cancer patients are being referred to hospitals out of the service area because Mission does not have adequate staffing to provide the quality of care local physicians demand for their patients.

The quality of care proposed by Novant is questionable as it intends to perform many of its surgical cases in three unlicensed procedure rooms. This is inconsistent with licensure regulations, Facility Guideline Institute ("FGI") hospitals guidelines, and the intent of the SMFP in requiring a hospital to provide surgical services. As noted above, the project will not increase either geographic or financial access to the service area. The reduction of ambulatory surgical facility services related to the operating room transfer will also negatively affect access and quality.

It is important to consider the exact language of G.S. 131E-183(a)(18a) in review of the Novant application:

> *(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.*

Novant will not have any positive impact on cost effectiveness, quality, and access to services. It is demonstrated throughout this document that the project proposed by Novant does not improve any of these required factors.

Novant should be found non-conforming with Criterion (18a).

Criterion (20) Quality

As discussed in detail in Criterion (1) above, Novant intends to obtain an OR for the proposed hospital through the sale and transfer of an ambulatory surgical facility OR for shared inpatient/outpatient use at

NH Asheville. This transaction is necessary for Novant to obtain a licensed OR because the 2024 SMFP shows no need for additional hospital-based operating rooms in the Buncombe County service area. This limits Novant's ability to apply for and receive an acute care operating room through an SMFP need determination.

On page 181, Novant presents its combined inpatient and outpatient surgical projections. These show a need for approximately 1.4 operating rooms in the proposed facility. In addition to the one transferred operating room discussed above, Novant proposes three unlicensed procedure rooms in its facility design. To address the need for more operating room capacity than Novant proposes to build, it intends to perform surgeries in its unlicensed procedure rooms. Specifically, it states, "Although NH Asheville will have only one OR, the projected surgical volume will be spread across one licensed OR and three unlicensed procedure rooms." In other words, these rooms will be used interchangeably, regardless of licensure status. Novant does not attempt to quantify the number or types of procedures that are performed in each type of room. This deficiency is poignant since one of the two partners in this project is a specialized surgical group, performing highly specialized oncology-related surgeries.

Novant clearly states its physicians will be performing complex oncology surgery in procedure rooms that are unlicensed and unregulated. Novant also proposes to be a "cancer hospital," but it will not have the basic components of a cancer center including such services as PET, MRI, radiation therapy, etc. Moreover, they do not indicate that they will have a range of specialists necessary to provide multidisciplinary cancer care. Indeed, Novant states it does not know what subspecialists will be on staff. All these facts call into question the quality of care.

Novant should be found non-conforming with Criterion (20).

Criteria and Standards – Novant's Project Does Not Conform to the Performance Standards for Acute Care Beds and Operating Rooms

Acute Care Bed Performance Standards

SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE BEDS
10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be **at least 66.7 percent when the projected ADC is less than 100 patients**, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

Novant's assumptions and basis for its inpatient utilization projections are flawed for the reasons discussed in detail under Criterion (3). Incorporating these flaws, Novant does not meet the required Acute Care Bed Performance Standards.

In addition, as demonstrated in the discussion regarding Criterion (3), even if Novant treated 80% of the 2023 cancer inpatients served in Buncombe and Henderson County hospitals, regardless of DRG or provider, originating from the eight-county service area, Novant would not meet the performance standards for new acute care beds. See **Figure 14** below. Novant's inpatient utilization projections are incorrect and do not meet this Standard.

Figure 14

Summary of Acute Care Bed Utilization for Clinically Appropriate Patients				
	2028	**2029**	**2030**	**2031**
Discharges	768	775	782	789
Patient Days	3,987	4,022	4,058	4,094
ALOS	5.19	5.19	5.19	5.19
ADC	10.92	11.02	11.12	11.22
Percent Capacity	**42.01%**	**42.38%**	**42.76%**	**43.14%**

Conclusion

It is clear that NH Asheville's project is designed to serve the needs of two physician practices and not the needs of the service area as a whole. Moreover, it is an incredibly expensive project that will only serve a very limited number and type of patients. NH Asheville should be found non-conforming with Criterion (1), (3), (4), (5), (6), (8), (13), (18a), (20) and should be denied.

Comparative Review of 2024 Buncombe County
Acute Care Bed CON Applications

Pursuant to G.S. 131E-183(a)(1) and the 2024 State Medical Facilities Plan ("SMFP"), no more than 26 acute care beds may be approved for the Buncombe/Graham/Madison/Yancey County service area in this review. Because the applications in the review collectively propose to develop 78 additional acute care beds in Buncombe County, all applicants cannot be approved for the total number of beds proposed. Therefore, after considering all review criteria, Mission conducted a comparative analysis of each proposal to demonstrate why Mission is the comparatively superior applicant and should be approved.

Below is a brief description of each project included in the Acute Care Bed Comparative Analysis.

- Project ID B-012526-24/**AdventHealth Asheville, Inc. ("AdventHealth") -** Develop 26 additional acute care beds at AdventHealth Asheville pursuant to the 2024 SMFP Need Determination. [1]
- Project ID B-012520-24/**Novant Health Asheville Medical Center, LLC ("Novant") -** Develop a new cancer-focused hospital with 26 acute care beds pursuant to the 2024 SMFP Need Determination.
- Project ID B-012518-24/**MH Mission Hospital, LLLP ("Mission") -** Develop 26 additional acute care beds at Mission's existing hospital in Asheville pursuant to the 2024 SMFP Need Determination.

The table below summarizes information from each application.

Facility Name	**Novant Health Asheville**	**AdventHealth Asheville**	**Mission Hospital**
Hospital Level of Care	Cancer-focused Community Hospital	Community Hospital	Tertiary Care Hospital
Number of Existing/Approved Beds	0	67	733
Beds Proposed to be Added	26	26	26
Total Number of Proposed Beds*	26	93	759
Third Full Fiscal Year	CY 2031	FY 2030	CY 2028
Projected Discharges - Year 3	1,036	6,120	45,279
Projected Acute Care Days - Year 3	6,976	24,703	253,597
% Occupancy - Year 3	73.5%	72.8%	91.5%

Source: Applications

**Proposed Beds = Number of existing beds + Number of Beds Requested in the application*

*** Assuming all beds requested by each applicant are approved*

Because of the significant differences in types of facilities, number of total acute care beds, number of projected acute care days and discharges, levels of patients acuity which can be served, total revenues and expenses, and differences in presentation of pro forma financial statements, some comparative factors may be of less value and result in less than definitive outcomes than if all applications were being reviewed for like facilities of similar size proposing similar services and using the same reporting formats.

[1] AdventHealth Asheville (Project ID#: B-012233-22) was recently approved but is being appealed further by Mission Hospital to the Court of Appeals.

In the following analysis, Mission describes the relative comparability of each competing applicant regarding the comparative factors typically used by the CON Section and further indicates which factors cannot be effectively compared in this review because of differences among the competing applicants.

Conformity with Review Criteria

Among the competing applicants, only the **Mission** application conforms with all applicable statutory and regulatory review criteria. **AdventHealth** and **Novant** do not conform to several statutory and regulatory review criteria. Please see detailed discussion under each criterion:

- AdventHealth and Novant are not conforming with the SMFP - Criterion (1).
    - Neither has documented that they are qualified applicants.
    - Neither has demonstrated that they will serve the population that generated the demand for beds in the 2024 SMFP.
- Novant fails to demonstrate a need for its project or that its project will enhance geographic access located right in between Mission Hospital and two community hospitals in Henderson County just to the south. – Criterion (3).
- The utilization projections for Novant and AdventHealth are both unsupported and unreasonable meaning they cannot be found conforming with Statutory Review Criterion (3) and the Acute Care Bed Performance Standards.
- AdventHealth and Novant's projects are not the least costly or most effective alternatives. – Criterion (4).
    - Approval of Novant would result in an underutilized, limited scope, small acute care hospital focused on serving the patients of just two physician practices.
    - Approval of additional beds at AdventHealth will result in a costly and unnecessary addition to a hospital that has not yet been built, opened, and is currently under appeal.
    - The approval of either Novant or AdventHealth will leave Mission with continuously high occupancy rates.
    - Only the approval of Mission will focus on the region's need for higher levels of care reflected in the ongoing need in the 2024 SFMP and address the exceedingly high and unsustainable occupancy rates at Mission Hospital.
- Due to the flawed utilization projections and related financial assumptions, neither AdventHealth nor Novant are financially feasible as presented – Criterion (5).
- Both Novant and AdventHealth represent unnecessary duplication of services. – Criterion (6).
    - AdventHealth represents a complete duplication of services offered by other small community hospitals already serving its proposed service areas that are not highly utilized and have adequate capacity to serve more patients.
    - Novant represents a duplication of cancer services and other surgical services already offered by Mission and routinely used by patients of the two practices that NH Asheville proposes to serve.

- Novant proposes duplicative and redundant ancillary and support services that are not needed and are projected to be highly underutilized as only beds are identified as needed in the SMFP. – Criterion (8).
- AdventHealth does not propose to offer a general licensed ORs and thus does not have the necessary ancillary services to operate a full-service community hospital with appropriate quality and safety standards. – Criterion (8).

- Neither AdventHealth nor Novant have reasonably documented their project and associated costs. – Criterion (12).
    - The cost of the new hospital proposed by Novant is exceedingly high, and not well documented.
    - The costs of AdventHealth's bed addition are unclear with no supporting detail as to what the additional costs involve.
- Neither AdventHealth nor Novant's site is appropriate and ready for development of a new hospital. – Criterion (12)
    - AdventHealth's site is comprised of multiple parcels, several of which are contingent on annexation by the town of Weaverville. All parcels require rezoning.
    - Novant's site is not appropriately zoned without obtaining special permits for a hospital location.
- Both AdventHealth and Novant project a payor mix that is not reflective of the demands of the service area. Criterion (13).
    - AdventHealth's payor mix is unclear as a result of the requested addition and change of location with no updated information is provided despite a significant change in the patient origin of the patients to be served.
    - Novant's payor mix is flawed as it is only based on the payor mix of two physician practices who have agreed to refer patients to its proposed hospital.
- Neither AdventHealth nor Novant conform with Criterion (18a).
    - The proposed projects from Novant and AdventHealth will not offer the range of services that actually created the bed need in the SMFP.
    - Novant will completely duplicate existing services in the market simply to meet the needs of two small physician practices.
- AdventHealth cannot meet the quality-of-care criterion or the requirements of the State's acute care licensure standards since it will not have an OR, and AdventHealth wrongly suggests that it is appropriate to offer "major surgical cases" in procedure rooms as opposed to ORs. Likewise, Novant states that the majority of its outpatient surgery cases will be performed in unlicensed procedure rooms and not in ORs as required. This similarly results in significant quality of care concerns – Criterion (20).

Therefore, **Mission** is the most effective alternative with regards to conformity with review criteria, and neither AdventHealth nor Novant are approvable.

Scope of Services

Generally, the application proposing to provide the broadest scope of services is the most effective alternative regarding this comparative factor.

Mission is an existing tertiary care provider that offers a broad range of medical and surgical services. **Mission** provides a comprehensive range of inpatient and outpatient services, including cardiology and cardiovascular surgery, general and urologic surgery, pediatrics, orthopedics, oncology, women's services, neurology, and trauma. Among the specialized programs and referral services offered at **Mission** are a state-designated high-risk pregnancy center, interventional cardiology (including cardiac catheterization, electrophysiology, and stents), cardiac surgery (including transcatheter aortic valve replacement, left ventricular assist device placement, structural heart, and bypass surgeries), inpatient dialysis, advanced imaging, and many others.

AdventHealth proposed adding beds to a small community hospital, and **Novant** proposed developing a new cancer-focused small community hospital. However, as a smaller community hospital, neither will provide a scope of services comparable to **Mission**, a Level II Adult trauma center, and a tertiary care provider. **Novant** and **AdventHealth** will not offer the range of services offered by **Mission**.

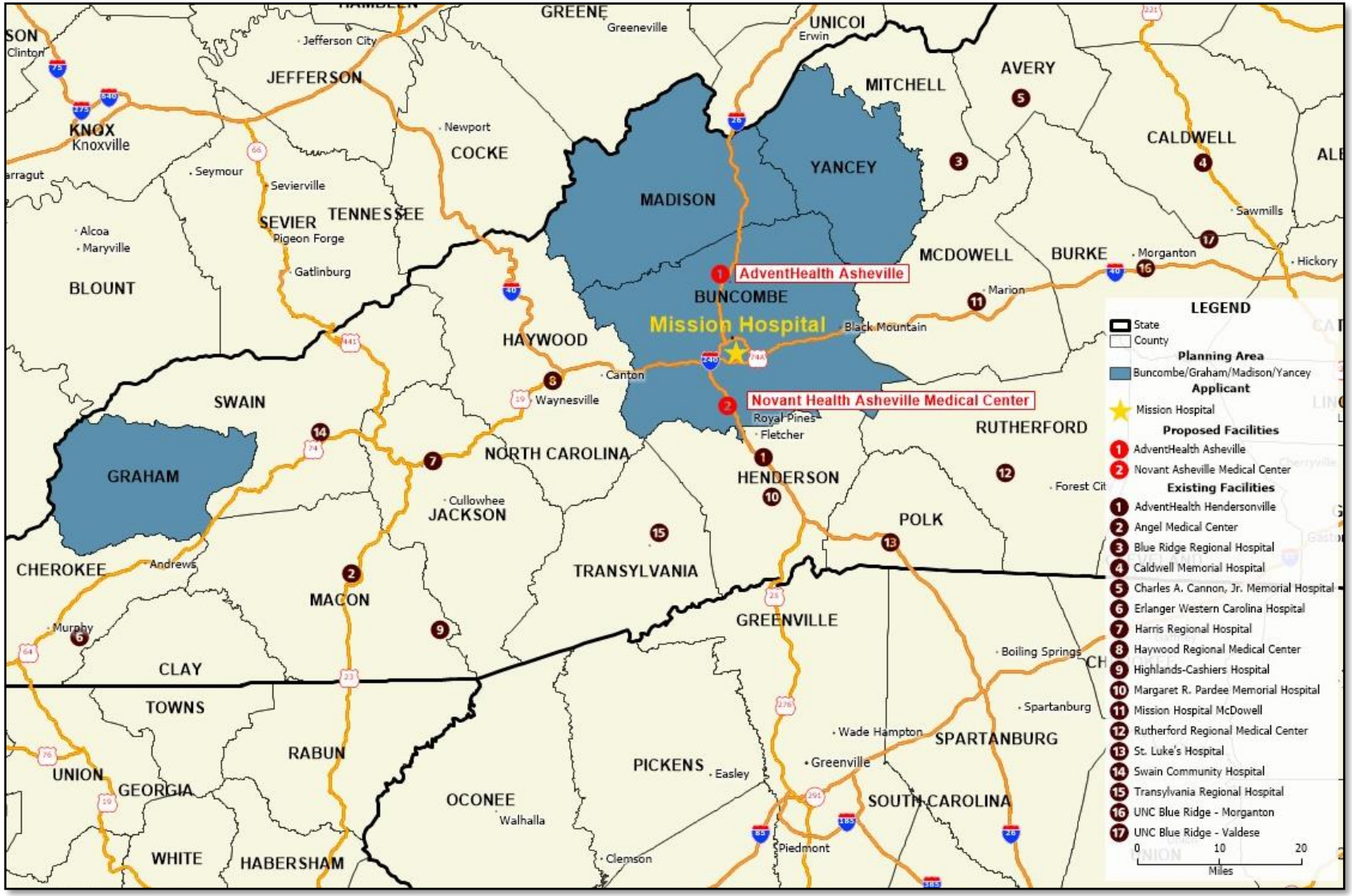
Therefore, **Mission** projects the broadest range of services, including those that drove the SMFP need for acute care beds in the service area, making it the most effective alternative with respect to this comparative factor. **AdventHealth** and **Novant** are the least effective alternatives.

Geographic Access

There are 749 existing and approved acute care beds (excluding NICU) in Buncombe County and none in Graham, Madison, and Yancey Counties, all part of the acute care planning area that generated the need. As shown in the map below, Buncombe County has one existing hospital, Mission Hospital, and one currently approved hospital, AdventHealth Asheville, that is not yet operational. **Mission** proposes adding 26 acute care beds to its existing facility, **AdventHealth** plans to add 26 beds to its approved and undeveloped hospital, and **Novant** proposes to develop a new low-acuity, cancer-focused hospital. The following maps show the locations of **Mission** and the proposed locations of **AdventHealth** and **Novant** as well as the other hospitals in the highlighted four-county, SMFP defined planning area and the surrounding areas of the western North Carolina region.

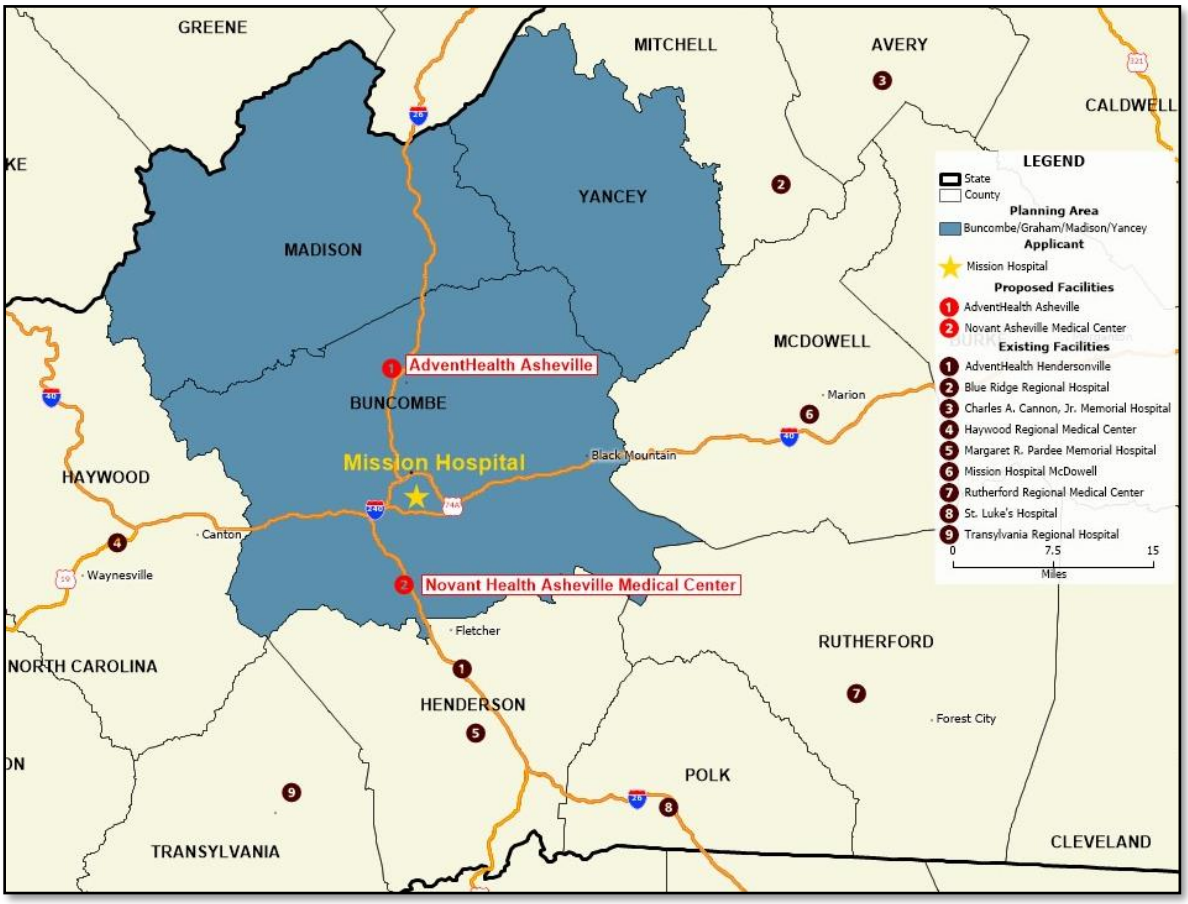
All three applicants propose to develop the acute beds in Buncombe County, within 20 miles of each other. **Novant's** proposed beds will not increase geographic access to community hospital services. It proposes to construct its hospital less than 15 miles from two existing acute care providers in Henderson County and less than ten miles from Mission Hospital. **AdventHealth's** newly proposed location in Weaverville is closer to Madison and Yancey Counties than the other applicants, and from this standpoint, will increase geographic access to acute care beds. However, AdventHealth will also take market share from other small community hospitals that currently serve Madison and Yancey Counties including Blue Ridge Regional Hospital and Duke LifePoint Haywood. Notably, **AdventHealth** will also take market share from its affiliate AdventHealth Hendersonville, although this is not considered in its projections. **Mission** is centrally located for all parts of Buncombe County and is the most accessible for residents of Graham County, who must travel from far western North Carolina and would practically have to pass Mission before traveling north to AdventHealth or south to Novant. **Mission** is the only applicant that will utilize the proposed 26-bed addition for the high acuity acute care services that generated the need for these beds in the SMFP. As a result, only **Mission** increases geographic access to acute care beds for their needed purpose. As a result, **Mission** is the most effective applicant with regard to geographic access. **AdventHealth** is effective but duplicative to other similar nearby providers, diluting the market, and **Novant** is not effective.

Buncombe, Graham, Madison and Yancey Planning Area with Existing and Approved Hospitals



Source: Maptitude

Buncombe, Madison, and Yancey Counties with Existing and Proposed Hospitals



Historical Utilization

The table below shows acute care bed utilization for existing facilities based on acute care beds and days reported on the 2024 LRAs, excluding NICU services days and beds. Generally, the applicant with the higher historical utilization is the more effective alternative with regards to this comparative analysis factor.

Historical Acute Care Bed Utilization Comparison*

Hospital/Applicant in Market	Beds	Patient Days	ADC	% Occupancy
Mission	682	216,600	593	**87.0%**
Advent Hendersonville	62	13,467	37	59.5%
Novant	NA	NA	NA	NA

Source: 2024 LRAs

**Acute care beds not including NICU services*

As shown in the Table above, **Mission's** historical utilization is higher than **AdventHealth's** existing facility, AdventHealth Hendersonville which is in Henderson County, bordering Buncombe County. **Novant** does not have an existing facility in or near the Buncombe County service area and thus has no historical utilization.

Therefore, a comparison of historical utilization cannot be effectively conducted between all three applicants. However, **Mission** is the most effective alternative among the two applicants with existing facilities in or near the service area, and its exceedingly high occupancy warrants consideration as a comparative factor.

Projected Utilization and Bed Capacity

The following table shows each facility's projected acute care bed utilization, excluding days and beds for NICU services. Generally, the applicant with the higher projected utilization is the more effective alternative regarding this comparative analysis factor in terms of the effectiveness of use of the proposed beds.

Projected Acute Care Bed Utilization Comparison - 3rd Full Fiscal Year*

Hospital/Applicant in Market	Beds	Admissions /Discharges	Patient Days	ADC	% Occupancy
Mission	636	38,113	218,491	598.61	**94.1%**
Advent**	93	6,120	24,703	67.68	72.8%
Novant	26	1,036	6,976	19.11	73.5%

Source: Each applications Form C.1b

**Acute care beds not including NICU services*

***Advent's projections are not reasonable as they include surgical inpatients with surgical cases that cannot be appropriately performed without an OR.*

As shown in the table above, **Mission's** projected utilization is higher than **AdventHealth's** and **Novant's.** As discussed above, there are also numerous flaws in the utilization assumptions and methodologies of both the **AdventHealth** and **Novant** proposals, which result in inaccurate and overstated projected utilization. Therefore, with regard to projected utilization, **Mission** is the most effective alternative; **AdventHealth** and **Novant** are the least effective alternatives.

Service to the Planning Area Counties (Access by Service Area Residents)

On page 31, the 2024 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Buncombe/Graham/Madison/Yancey Counties as the acute bed service area. Thus, the service area for this review is Buncombe/Graham/Madison/Yancey Counties. Facilities may also serve residents of counties not included in the service area. Generally, the application with projections indicating the most accessibility to Buncombe/Graham/Madison/Yancey County residents is the most effective alternative with regards to this comparative factor.

Inpatient Admissions from the SMFP Acute Care Planning Area

	Advent*		Novant		Mission	
	3rd Full FY		3rd Full FY		3rd Full FY	
Buncombe	4,360	79.2%	486	85.6%	21,635	86.2%
Madison	556	10.1%	48	8.5%	2,049	8.2%
Yancey	488	8.9%	27	4.8%	1,130	4.5%
Graham	103	1.9%	7	1.2%	298	1.2%
Total Planning Area	**5,507**	**100.0%**	**568**	**100.0%**	**25,112**	**100.0%**

Sources: Applications, Section C, Projected Patient Origin

**Advent's projections are flawed by the inclusion of surgical cases that cannot be performed without an OR.*

The table above shows the patient origin for admissions from the SMFP acute care planning area for each proposed facility. It is important that the agency look beyond a simple percentage when evaluating this factor and evaluate the specific function these beds will serve and whether the proposed use of the beds meets a need for the SMFP acute care service area. As a regional tertiary provider and trauma center, Mission serves patients from all parts of western North Carolina and beyond. As a result, its percentages are not comparable to a community hospital with a smaller service area. A simplistic analysis ignores this significant role and can in fact penalize the applicant serving a significant percentage of patients from outside the planning area due to its high acuity service offerings.

The table shows that **Mission** projects to serve the most patients in the SMFP planning area counties, including the most patients from Madison, Yancey, and Graham Counties. Both **AdventHealth** and **Novant** projects to serve a small fraction of the total service area patients projected by **Mission,** particularly for Madison, Yancey, and Graham Counties. It should be noted that **AdventHealth's** patient origin is flawed by the unexplained doubling of its projected market share for Madison, Graham, and Yancey Counties. While it may project a higher percentage of patients from these counties, the projection is not realistic. A small, low acuity, community hospital with limited services is not going to draw a larger percentage of patients from distant counties than a large tertiary, trauma center.

Therefore, with regard to service to the planning area, **Mission** is the most effective alternative, and **Novant** and **AdventHealth** are the least effective alternatives.

Access by Underserved Groups

"Underserved groups" is defined in G.S. 131E-183(a)(13) as follows:

> *"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."*

For access by underserved groups, the applications in this review are compared with respect to three underserved groups: Charity Care patients (i.e., medically indigent, or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor.

Projected Charity Care

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

Projected Charity Care - 3rd Full Fiscal Year				
Applicant	**Charity Care Revenue**	**Admissions/ Discharges**	**Estimated Charity Admissions**	**% of Total Gross Patient Revenue**
Mission*	$165,454,871	38,113	1,197	3.14%
Advent**	$19,716,743	6,120	257	4.21%
Novant	$10,245,189	1,036	54	5.22%

Source: Application Form F.2b and Form C.1b

**Mission provides a pro forma for only inpatient adult medical/surgical services that will be impacted by the proposed project.*

***Advent projects charity care patients in Section L of the Original CON (B-012233-22) but does not update Section L in its change of scope application. The equivalent of only 257 patients in Section Q. Form F.2B Cost Overrun Application.*

Due to the differences in the presentation of pro forma financial statements, the number of patients, and the level of care at each facility, it is impossible to effectively compare the applicants based on this comparative factor. **Mission**, an existing large tertiary care center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than the other applicants. **Mission** provides a projection for inpatient adult services only, the service affected by their project. **Novant** and **AdventHealth** both provide a total hospital pro forma. Projected charity care cannot be compared. Further, even if the applicants provided pro forma statements in a comparable format with similar data, differences in patient acuity and levels of care at each facility would render any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicare

The following table shows projected Medicare during the third full fiscal year after each applicant's project completion Generally, the application with the highest projected provision of services to those with Medicare is the more effective alternative regarding this comparative factor.

Projected Medicare Revenue - 3rd Full Fiscal Year				
Applicant	**Medicare Revenue**	**Admissions/ Discharges**	**Estimated Medicare Admissions**	**% of Total Gross Patient Revenue**
Mission*	$3,045,062,572	38,113	22,036	57.82%
Advent	$284,628,782	6,120	3,715	60.71%
Novant	$99,576,949	1,036	526	50.75%

Source: Application Form F.2b and Form C.1b

**Mission provides a pro forma for only inpatient adult medical/surgical services that will be impacted by the proposed project.*

Due to the differences in the presentation of pro forma financial statements, the number of patients, and the level of care at each facility, it is impossible to effectively compare the applicants based on this comparative factor. **Mission**, an existing large tertiary care center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **AdventHealth** and **Novant**. **Mission** provides a projection for inpatient adult services only, the service affected by its project. **Novant** and **AdventHealth** both provide a total hospital pro forma. Projected Medicare cannot be compared.

Further, even if the applicants provided pro forma statements in a comparable format with similar data, differences in patient acuity and levels of care at each facility would render any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows projected Medicaid during the third full fiscal year following the completion of the project for each applicant. Generally, the application with the highest projected provision of services to those with Medicaid is the more effective alternative with regard to this comparative factor.

Projected Medicaid Revenue - 3rd Full Fiscal Year				
Applicant	**Medicaid Revenue**	**Admissions/ Discharges**	**Estimated Medicaid Admission**	**% of Total Gross Patient Revenue**
Mission*	$605,161,553	38,113	4,379	11.49%
Advent	$32,917,343	6,120	430	7.02%
Novant	$23,324,538	1,036	123	11.89%

Source: Application Form F.2b and Form C.1b

**Mission provides a pro forma for only inpatient adult medical/surgical services that will be impacted by the proposed project.*

Due to the differences in the presentation of pro forma financial statements, the number of patients, and the level of care at each facility, it is impossible to effectively compare the applicants based on this comparative factor. **Mission**, an existing large tertiary care center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **Novant** and **AdventHealth**. **Mission** provides a projection for inpatient adult services only, the service affected by its project. **Novant** and **AdventHealth** both provide a total hospital pro forma. Projected Medicaid cannot be compared.

Further, even if the applicants provided pro forma statements in a comparable format with similar data, differences in patient acuity and levels of care at each facility would render any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Average Net Revenue per Admission

The following table shows the projected average net revenue per admission in the third full fiscal year following project completion for each applicant. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative regarding this comparative factor. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, etc.) at each facility, and the number and types of surgical services proposed by each facility significantly impacts the simple averages shown in the table below.

Projected Average Revenue per Admission - 3rd Full FY

Applicant	**Total Admissions**	**Gross Revenue**	**Average Net Rev per Admission**
Mission	38,113	$5,266,557,559	$25,642
Advent	6,120	$468,831,242	$21,805
Novant	1,036	$196,193,488	$51,292

Note: Includes outpatient revenue as reported in total on Form F.2b

Therefore, given the extreme variation in service offerings and acuity levels between the applicants, this comparative factor is inconclusive. Also, **Novant's** average net revenue is more than double the net revenue for tertiary services offered by **Mission.** This further raises questions about the validity of Novant's projections.

Projected Average Expenses per Admission

Total Expense

The following table shows the projected average expense per admission in the third full fiscal year following project completion for each applicant. Generally, the application projecting the lowest average total expense per surgical case is the more effective alternative with regard to this comparative factor. However, in this instance the service offerings between a regional tertiary trauma provider and two small community hospitals cannot be compared which renders a comparison inconclusive.

Projected Average Expense per Admission - 3rd Full FY

Applicant	Total Admissions	Total Expense	Average Expense per Admission
Mission	38,113	$640,289,776	$16,800
Advent	6,120	$80,029,174	$13,077
Novant	1,036	$52,053,597	$50,245

Therefore, given the extreme variation in service offerings and acuity levels between the applicants, this comparative factor is inconclusive. It is interesting, however, that **Novant's** average expense per admission is more than three times the net revenue for tertiary services offered by **Mission.** This further raises questions about the validity of Novant's projections.

Project Costs

The table below shows the projected cost for each project. Generally, the applicant who projects the lowest project cost should be found to be the most effective alternative regarding this comparative analysis factor based on the directive of the CON Statute to contain costs. The Agency does not always consider project cost in the comparatives analysis, but cost containment is a basic premise of the CON statute. In this instance there are three proposals to bring 26 beds to the community which contain three vastly different costs. Thus, the cost effectiveness of the project should be considered in this comparative analysis.

Applicant	Project Cost	Variance from Low Cost Option	Cost per Bed
Mission	$1,621,000		$62,346
Advent*	$109,203,668	$107,582,668	$4,200,141
Novant	$249,475,340	$247,854,340	$9,595,205

Source: Form F.1a

**Advent Project cost only reflects the additional cost to add 26 beds to previously approved project.*

As displayed in the table above, **Mission** has the lowest project cost with Advent over $100 million higher and **Novant** almost $250 million higher. **AdventHealth** has the second lowest cost. **Novant** has the highest project cost, which is the highest project cost per bed among small hospitals approved since 2019.

Therefore, in regard to cost, **Mission** has the lowest project cost making it the most effective applicant. **Novant** and **AdventHealth** are the least effective alternatives.

Project Timing

The table below shows the date when the acute care beds will come online (when beds will be available for use) as reported in each applicant's proposal. Generally, the applicant who can have beds available the soonest is the most effective alternative regarding this comparative analysis factor. While the Agency does not always consider this factor, it is relevant as to how quickly the needs of the patients in the service area and the need identified in the SMFP can be met.

Beds Online and Available

	Date Beds Come Online	Variance from Earliest Date Option
Mission	7/1/2025	
Advent	10/1/2027	2 1/4 Years
Novant	12/1/2028	3 1/2 Years

Source: Applications

As shown in the table above, **Mission** will be the first to get beds online. Upon approval of its application, **Mission** can bring all 26 beds online in July 2025. As mentioned in **Mission's** application, **Mission** is experiencing incredibly high occupancy rates and growing demand for its high acuity services, factors that actually generated the bed need in the 2024 SMFP. If **AdventHealth** is approved, it plans to have the 26 beds online in October 2027, which is two and a quarter years after **Mission**. Additionally, the approved hospital where **AdventHealth** plans to add these beds has yet to begin construction, and the project's decision was recently appealed to the Court of Appeals, making it unclear when construction can even begin. **Novant** projects an even later date to bring beds online, which is three and a half years later than Mission's beds would begin serving patients. It should also be noted that both **AdventHealth** and **Novant** require property status changes and rezoning that can often result in years of delay, which has happened for other recent new hospital projects. Both of their timelines assume no delays.

Therefore, with regard to timing, **Mission** will have beds online more quickly than the other applicants. **Mission** is the most effective alternative regarding this comparative factor.

Competition (Patient Access to a New or Alternative Provider)

There are 800 existing and approved acute care beds located in Buncombe County and no acute care hospital beds in Graham, Madison, and Yancey Counties. Graham, Madison, and Yancey Counties are included in the planning area for the calculation of the bed need methodology due to their reliance on Mission as the regional tertiary care and trauma provider. However, planning area residents utilize numerous other community and rural hospitals in the region including UNC Pardee Hospital, AdventHealth Hendersonville, Haywood Regional Medical Center, Blue Ridge Regional Hospital, Swain County Community Hospital, and Duke Life Point Harris Regional Hospital, among others.

Mission is the only regional tertiary hospital and trauma services provider and the only applicant proposing to use the 26 acute care beds for services that are critical to the region. **AdventHealth** and **Novant** propose to use the 26 acute care beds in small community hospitals with a limited range of services at a time when there are already multiple community hospitals in the area with adequate capacity and offering the same services as those proposed by **AdventHealth** and **Novant**. **AdventHealth**'s project simply adds additional beds to an approved facility that is years from opening and does not enhance competition. **Novant**'s project proposes the development of beds for a limited cancer need, which it does not demonstrate exists. In addition, **Novant**'s entire service area and utilization is based on the provision of services to the patients of two referring providers. It is not seeking to serve the community at large. Further, Novant's project does not increase geographic access given that it is less than 15 miles from two community hospitals located in Henderson County.

In the past, the Agency has taken a rather one-dimensional approach to the competition comparative factor, often concluding that any new provider is a more effective alternative. This approach ignores or overlooks that the high and often specialized utilization of existing providers generated the need in the SMFP for a given review and that often the provider generating the need offers more complex and diverse services than those which can be offered by a new provider. These circumstances are applicable to this review.

Moreover, the cost to establish a new provider or facility is generally far higher than adding the needed beds or services to existing facilities that created the SMFP need. In such cases, approving a new provider simply because they represent new a new provider represents a costly duplication of services. Mission encourages the Agency to consider the competition factor in combination with other equally important CON Statutory criteria, such as unnecessary duplication of services, limiting costs, and serving the needs of the service area population based on the scope of services provided. This balancing of criteria is specifically directed by the SHCC on page 3 of the 2024 SMFP.

A key component in evaluating this comparative factor is the consideration of whether the applicants propose to provide and deliver like services to similar populations by the applicants. In this instance, neither **AdventHealth** nor **Novant** propose to offer like services to those already offered by **Mission** including high acuity, tertiary, and specialty care, which **Mission** proposes to expand. Further, there is underutilized capacity in the region for the services proposed by both **AdventHealth** and **Novant.** However, there are aspects of each proposal that can be compared in this comparative factor, including quality, safety, access, cost effectiveness and value. The table below provides such a comparison.

In this review, **Mission**'s project is the least costly and offers the highest acuity and broadest range of services. For these reasons, the Agency should find that the competition comparative factor is either inconclusive, due to fact that "like services" are not proposed by the applicants or find that **Mission** is the most effective alternative because it offers the highest acuity and broadest range of services

Conclusion

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during the review would result in acute care beds in excess of the need determination in Buncombe/Graham/Madison/Yancey Counties service area. Only **Mission's** project can be approved as it is the only applicant that conforms to all project review criteria and applicable performance standards. However, if all applicants were approvable based on these criteria, **Mission's** project is still the most effective alternative to meet the need based on the summary below. As such, **Mission's** project should be approved.

Summary of Comparative Factors

Meaure/Analysis	**Mission**	**Advent**	**Novant**
Conformity with Review Criteria	Yes	No	No
Scope of Services	Most Effective	Least Effective	Least Effective
Geographic Access	Most Effective	Effective	Least Effective
Historical Utilization	Most Effective	Least Effective	NA
Projected Utilization / Use of Beds	Most Effective	Least Effective	Least Effective
Competition/Access to New Provider	Most Effective	Inconclusive	Inconclusive
Service to the Planning Area Counties (a)	Most Effective	Least Effective	Least Effective
Projected Financial Access	Most Effective	Least Effective	Least Effective
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Admission	Inconclusive	Inconclusive	Inconclusive
Projected Average Expense per Admission	Inconclusive	Inconclusive	Inconclusive
Project Cost	Most Effective	Least Effective	Least Effective
Project Timing	Most Effective	Least Effective	Least Effective

(a) Given the variation in types of projects (small community hospitals v. regional tertiary medical center), the most reasonable method to compare service to the planning area counties is the number of patients served.

Attachment A

Novant's Exhibit C-1.2 – NH Ashville DRGs

DRG	DRG Description
4	TRACHEOSTOMY WITH MV >96 HOURS OR PRINCIPAL DIAGNOSIS EXCEPT FACE, MOUTH AND NECK WITHOUT MAJOR O.R. PROCEDURES
11	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITH MCC
12	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITH CC
13	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITHOUT CC/MCC
18	CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL AND OTHER IMMUNOTHERAPIES
23	CRANIOTOMY WITH MAJOR DEVICE IMPLANT OR ACUTE COMPLEX CNS PRINCIPAL DIAGNOSIS WITH MCC OR CHEMOTHERAPY IMPLANT OR EPILEPSY WITH NEUROSTIMULATOR
28	SPINAL PROCEDURES WITH MCC
54	NERVOUS SYSTEM NEOPLASMS WITH MCC
55	NERVOUS SYSTEM NEOPLASMS WITHOUT MCC
57	DEGENERATIVE NERVOUS SYSTEM DISORDERS WITHOUT MCC
64	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION WITH MCC
65	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION WITH CC OR TPA IN 24 HOURS
66	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION WITHOUT CC/MCC
70	NONSPECIFIC CEREBROVASCULAR DISORDERS WITH MCC
73	CRANIAL AND PERIPHERAL NERVE DISORDERS WITH MCC
74	CRANIAL AND PERIPHERAL NERVE DISORDERS WITHOUT MCC
81	NONTRAUMATIC STUPOR AND COMA WITHOUT MCC
82	TRAUMATIC STUPOR AND COMA >1 HOUR WITH MCC
85	TRAUMATIC STUPOR AND COMA <1 HOUR WITH MCC
92	OTHER DISORDERS OF NERVOUS SYSTEM WITH CC
93	OTHER DISORDERS OF NERVOUS SYSTEM WITHOUT CC/MCC
94	BACTERIAL AND TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM WITH MCC
95	BACTERIAL AND TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM WITH CC
97	NON-BACTERIAL INFECTION OF NERVOUS SYSTEM EXCEPT VIRAL MENINGITIS WITH MCC
98	NON-BACTERIAL INFECTION OF NERVOUS SYSTEM EXCEPT VIRAL MENINGITIS WITH CC
100	SEIZURES WITH MCC
101	SEIZURES WITHOUT MCC
103	HEADACHES WITHOUT MCC
113	ORBITAL PROCEDURES WITH CC/MCC
123	NEUROLOGICAL EYE DISORDERS
137	MOUTH PROCEDURES WITH CC/MCC
140	MAJOR HEAD AND NECK PROCEDURES WITH MCC
141	MAJOR HEAD AND NECK PROCEDURES WITH CC
142	MAJOR HEAD AND NECK PROCEDURES WITHOUT CC/MCC
144	OTHER EAR, NOSE, MOUTH AND THROAT O.R. PROCEDURES WITH CC
145	OTHER EAR, NOSE, MOUTH AND THROAT O.R. PROCEDURES WITHOUT CC/MCC
146	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITH MCC
147	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITH CC
148	EAR, NOSE, MOUTH AND THROAT MALIGNANCY WITHOUT CC/MCC
157	DENTAL AND ORAL DISEASES WITH MCC
158	DENTAL AND ORAL DISEASES WITH CC
166	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC
167	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC
168	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITHOUT CC/MCC
175	PULMONARY EMBOLISM WITH MCC OR ACUTE COR PULMONALE
176	PULMONARY EMBOLISM WITHOUT MCC
177	RESPIRATORY INFECTIONS AND INFLAMMATIONS WITH MCC
178	RESPIRATORY INFECTIONS AND INFLAMMATIONS WITH CC
179	RESPIRATORY INFECTIONS AND INFLAMMATIONS WITHOUT CC/MCC
180	RESPIRATORY NEOPLASMS WITH MCC
181	RESPIRATORY NEOPLASMS WITH CC
182	RESPIRATORY NEOPLASMS WITHOUT CC/MCC
183	MAJOR CHEST TRAUMA WITH MCC
187	PLEURAL EFFUSION WITH CC
188	PLEURAL EFFUSION WITHOUT CC/MCC
189	PULMONARY EDEMA AND RESPIRATORY FAILURE
190	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH MCC
191	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH CC
193	SIMPLE PNEUMONIA AND PLEURISY WITH MCC
194	SIMPLE PNEUMONIA AND PLEURISY WITH CC
196	INTERSTITIAL LUNG DISEASE WITH MCC
197	INTERSTITIAL LUNG DISEASE WITH CC
198	INTERSTITIAL LUNG DISEASE WITHOUT CC/MCC
200	PNEUMOTHORAX WITH CC
204	RESPIRATORY SIGNS AND SYMPTOMS
205	OTHER RESPIRATORY SYSTEM DIAGNOSES WITH MCC
206	OTHER RESPIRATORY SYSTEM DIAGNOSES WITHOUT MCC
207	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT >96 HOURS
208	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT <=96 HOURS
264	OTHER CIRCULATORY SYSTEM O.R. PROCEDURES
312	SYNCOPE AND COLLAPSE
313	CHEST PAIN
326	STOMACH, ESOPHAGEAL AND DUODENAL PROCEDURES WITH MCC
327	STOMACH, ESOPHAGEAL AND DUODENAL PROCEDURES WITH CC
328	STOMACH, ESOPHAGEAL AND DUODENAL PROCEDURES WITHOUT CC/MCC
329	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITH MCC
330	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITH CC
331	MAJOR SMALL AND LARGE BOWEL PROCEDURES WITHOUT CC/MCC
333	RECTAL RESECTION WITH CC
334	RECTAL RESECTION WITHOUT CC/MCC
335	PERITONEAL ADHESIOLYSIS WITH MCC
336	PERITONEAL ADHESIOLYSIS WITH CC
337	PERITONEAL ADHESIOLYSIS WITHOUT CC/MCC
338	APPENDECTOMY WITH COMPLICATED PRINCIPAL DIAGNOSIS WITH MCC

DRG	DRG Description
339	APPENDECTOMY WITH COMPLICATED PRINCIPAL DIAGNOSIS WITH CC
342	APPENDECTOMY WITHOUT COMPLICATED PRINCIPAL DIAGNOSIS WITH CC
343	APPENDECTOMY WITHOUT COMPLICATED PRINCIPAL DIAGNOSIS WITHOUT CC/MCC
345	MINOR SMALL AND LARGE BOWEL PROCEDURES WITH CC
347	ANAL AND STOMAL PROCEDURES WITH MCC
348	ANAL AND STOMAL PROCEDURES WITH CC
349	ANAL AND STOMAL PROCEDURES WITHOUT CC/MCC
354	HERNIA PROCEDURES EXCEPT INGUINAL AND FEMORAL WITH CC
355	HERNIA PROCEDURES EXCEPT INGUINAL AND FEMORAL WITHOUT CC/MCC
356	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES WITH MCC
357	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES WITH CC
358	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES WITHOUT CC/MCC
371	MAJOR GASTROINTESTINAL DISORDERS AND PERITONEAL INFECTIONS WITH MCC
372	MAJOR GASTROINTESTINAL DISORDERS AND PERITONEAL INFECTIONS WITH CC
373	MAJOR GASTROINTESTINAL DISORDERS AND PERITONEAL INFECTIONS WITHOUT CC/MCC
374	DIGESTIVE MALIGNANCY WITH MCC
375	DIGESTIVE MALIGNANCY WITH CC
376	DIGESTIVE MALIGNANCY WITHOUT CC/MCC
377	GASTROINTESTINAL HEMORRHAGE WITH MCC
378	GASTROINTESTINAL HEMORRHAGE WITH CC
379	GASTROINTESTINAL HEMORRHAGE WITHOUT CC/MCC
380	COMPLICATED PEPTIC ULCER WITH MCC
381	COMPLICATED PEPTIC ULCER WITH CC
382	COMPLICATED PEPTIC ULCER WITHOUT CC/MCC
384	UNCOMPLICATED PEPTIC ULCER WITHOUT MCC
385	INFLAMMATORY BOWEL DISEASE WITH MCC
386	INFLAMMATORY BOWEL DISEASE WITH CC
387	INFLAMMATORY BOWEL DISEASE WITHOUT CC/MCC
388	GASTROINTESTINAL OBSTRUCTION WITH MCC
389	GASTROINTESTINAL OBSTRUCTION WITH CC
390	GASTROINTESTINAL OBSTRUCTION WITHOUT CC/MCC
391	ESOPHAGITIS, GASTROENTERITIS AND MISCELLANEOUS DIGESTIVE DISORDERS WITH MCC
392	ESOPHAGITIS, GASTROENTERITIS AND MISCELLANEOUS DIGESTIVE DISORDERS WITHOUT MCC
393	OTHER DIGESTIVE SYSTEM DIAGNOSES WITH MCC
394	OTHER DIGESTIVE SYSTEM DIAGNOSES WITH CC
395	OTHER DIGESTIVE SYSTEM DIAGNOSES WITHOUT CC/MCC
405	PANCREAS, LIVER AND SHUNT PROCEDURES WITH MCC
406	PANCREAS, LIVER AND SHUNT PROCEDURES WITH CC
407	PANCREAS, LIVER AND SHUNT PROCEDURES WITHOUT CC/MCC
408	BILIARY TRACT PROCEDURES EXCEPT ONLY CHOLECYSTECTOMY WITH OR WITHOUT C.D.E. WITH MCC
409	BILIARY TRACT PROCEDURES EXCEPT ONLY CHOLECYSTECTOMY WITH OR WITHOUT C.D.E. WITH CC
410	BILIARY TRACT PROCEDURES EXCEPT ONLY CHOLECYSTECTOMY WITH OR WITHOUT C.D.E. WITHOUT CC/MCC
413	CHOLECYSTECTOMY WITH C.D.E. WITHOUT CC/MCC
414	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE WITHOUT C.D.E. WITH MCC
415	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE WITHOUT C.D.E. WITH CC
416	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE WITHOUT C.D.E. WITHOUT CC/MCC
417	LAPAROSCOPIC CHOLECYSTECTOMY WITHOUT C.D.E. WITH MCC
418	LAPAROSCOPIC CHOLECYSTECTOMY WITHOUT C.D.E. WITH CC
419	LAPAROSCOPIC CHOLECYSTECTOMY WITHOUT C.D.E. WITHOUT CC/MCC
421	HEPATOBILIARY DIAGNOSTIC PROCEDURES WITH CC
422	HEPATOBILIARY DIAGNOSTIC PROCEDURES WITHOUT CC/MCC
423	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES WITH MCC
424	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES WITH CC
432	CIRRHOSIS AND ALCOHOLIC HEPATITIS WITH MCC
433	CIRRHOSIS AND ALCOHOLIC HEPATITIS WITH CC
435	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS WITH MCC
436	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS WITH CC
437	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS WITHOUT CC/MCC
438	DISORDERS OF PANCREAS EXCEPT MALIGNANCY WITH MCC
439	DISORDERS OF PANCREAS EXCEPT MALIGNANCY WITH CC
440	DISORDERS OF PANCREAS EXCEPT MALIGNANCY WITHOUT CC/MCC
441	DISORDERS OF LIVER EXCEPT MALIGNANCY, CIRRHOSIS OR ALCOHOLIC HEPATITIS WITH MCC
444	DISORDERS OF THE BILIARY TRACT WITH MCC
445	DISORDERS OF THE BILIARY TRACT WITH CC
446	DISORDERS OF THE BILIARY TRACT WITHOUT CC/MCC
453	COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION WITH MCC
456	SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH MCC
459	SPINAL FUSION EXCEPT CERVICAL WITH MCC
477	BIOPSIES OF MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITH MCC
478	BIOPSIES OF MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITH CC
479	BIOPSIES OF MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITHOUT CC/MCC
492	LOWER EXTREMITY AND HUMERUS PROCEDURES EXCEPT HIP, FOOT AND FEMUR WITH MCC
501	SOFT TISSUE PROCEDURES WITH CC
502	SOFT TISSUE PROCEDURES WITHOUT CC/MCC
512	SHOULDER, ELBOW OR FOREARM PROCEDURES, EXCEPT MAJOR JOINT PROCEDURES WITHOUT CC/MCC
515	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITH MCC
516	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITH CC
517	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE O.R. PROCEDURES WITHOUT CC/MCC
536	FRACTURES OF HIP AND PELVIS WITHOUT MCC
540	OSTEOMYELITIS WITH CC
551	MEDICAL BACK PROBLEMS WITH MCC
552	MEDICAL BACK PROBLEMS WITHOUT MCC
556	SIGNS AND SYMPTOMS OF MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITHOUT MCC
557	TENDONITIS, MYOSITIS AND BURSITIS WITH MCC
560	AFTERCARE, MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE WITH CC

DRG	DRG Description
562	FRACTURE, SPRAIN, STRAIN AND DISLOCATION EXCEPT FEMUR, HIP, PELVIS AND THIGH WITH MCC
564	OTHER MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE DIAGNOSES WITH MCC
571	SKIN DEBRIDEMENT WITH CC
572	SKIN DEBRIDEMENT WITHOUT CC/MCC
577	SKIN GRAFT EXCEPT FOR SKIN ULCER OR CELLULITIS WITH CC
578	SKIN GRAFT EXCEPT FOR SKIN ULCER OR CELLULITIS WITHOUT CC/MCC
579	OTHER SKIN, SUBCUTANEOUS TISSUE AND BREAST PROCEDURES WITH MCC
580	OTHER SKIN, SUBCUTANEOUS TISSUE AND BREAST PROCEDURES WITH CC
581	OTHER SKIN, SUBCUTANEOUS TISSUE AND BREAST PROCEDURES WITHOUT CC/MCC
582	MASTECTOMY FOR MALIGNANCY WITH CC/MCC
583	MASTECTOMY FOR MALIGNANCY WITHOUT CC/MCC
584	BREAST BIOPSY, LOCAL EXCISION AND OTHER BREAST PROCEDURES WITH CC/MCC
585	BREAST BIOPSY, LOCAL EXCISION AND OTHER BREAST PROCEDURES WITHOUT CC/MCC
596	MAJOR SKIN DISORDERS WITHOUT MCC
597	MALIGNANT BREAST DISORDERS WITH MCC
598	MALIGNANT BREAST DISORDERS WITH CC
603	CELLULITIS WITHOUT MCC
606	MINOR SKIN DISORDERS WITH MCC
607	MINOR SKIN DISORDERS WITHOUT MCC
624	SKIN GRAFTS AND WOUND DEBRIDEMENT FOR ENDOCRINE, NUTRITIONAL AND METABOLIC DISORDERS WITHOUT CC/MCC
626	THYROID, PARATHYROID AND THYROGLOSSAL PROCEDURES WITH CC
627	THYROID, PARATHYROID AND THYROGLOSSAL PROCEDURES WITHOUT CC/MCC
628	OTHER ENDOCRINE, NUTRITIONAL AND METABOLIC O.R. PROCEDURES WITH MCC
629	OTHER ENDOCRINE, NUTRITIONAL AND METABOLIC O.R. PROCEDURES WITH CC
638	DIABETES WITH CC
640	MISCELLANEOUS DISORDERS OF NUTRITION, METABOLISM, FLUIDS AND ELECTROLYTES WITH MCC
641	MISCELLANEOUS DISORDERS OF NUTRITION, METABOLISM, FLUIDS AND ELECTROLYTES WITHOUT MCC
643	ENDOCRINE DISORDERS WITH MCC
644	ENDOCRINE DISORDERS WITH CC
645	ENDOCRINE DISORDERS WITHOUT CC/MCC
653	MAJOR BLADDER PROCEDURES WITH MCC
654	MAJOR BLADDER PROCEDURES WITH CC
655	MAJOR BLADDER PROCEDURES WITHOUT CC/MCC
656	KIDNEY AND URETER PROCEDURES FOR NEOPLASM WITH MCC
657	KIDNEY AND URETER PROCEDURES FOR NEOPLASM WITH CC
658	KIDNEY AND URETER PROCEDURES FOR NEOPLASM WITHOUT CC/MCC
659	KIDNEY AND URETER PROCEDURES FOR NON-NEOPLASM WITH MCC
660	KIDNEY AND URETER PROCEDURES FOR NON-NEOPLASM WITH CC
661	KIDNEY AND URETER PROCEDURES FOR NON-NEOPLASM WITHOUT CC/MCC
662	MINOR BLADDER PROCEDURES WITH MCC
663	MINOR BLADDER PROCEDURES WITH CC
665	PROSTATECTOMY WITH MCC
666	PROSTATECTOMY WITH CC
667	PROSTATECTOMY WITHOUT CC/MCC
668	TRANSURETHRAL PROCEDURES WITH MCC
669	TRANSURETHRAL PROCEDURES WITH CC
670	TRANSURETHRAL PROCEDURES WITHOUT CC/MCC
671	URETHRAL PROCEDURES WITH CC/MCC
672	URETHRAL PROCEDURES WITHOUT CC/MCC
673	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITH MCC
674	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITH CC
675	OTHER KIDNEY AND URINARY TRACT PROCEDURES WITHOUT CC/MCC
682	RENAL FAILURE WITH MCC
683	RENAL FAILURE WITH CC
684	RENAL FAILURE WITHOUT CC/MCC
686	KIDNEY AND URINARY TRACT NEOPLASMS WITH MCC
687	KIDNEY AND URINARY TRACT NEOPLASMS WITH CC
688	KIDNEY AND URINARY TRACT NEOPLASMS WITHOUT CC/MCC
689	KIDNEY AND URINARY TRACT INFECTIONS WITH MCC
690	KIDNEY AND URINARY TRACT INFECTIONS WITHOUT MCC
694	URINARY STONES WITHOUT MCC
695	KIDNEY AND URINARY TRACT SIGNS AND SYMPTOMS WITH MCC
696	KIDNEY AND URINARY TRACT SIGNS AND SYMPTOMS WITHOUT MCC
698	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH MCC
699	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITH CC
700	OTHER KIDNEY AND URINARY TRACT DIAGNOSES WITHOUT CC/MCC
707	MAJOR MALE PELVIC PROCEDURES WITH CC/MCC
708	MAJOR MALE PELVIC PROCEDURES WITHOUT CC/MCC
709	PENIS PROCEDURES WITH CC/MCC
710	PENIS PROCEDURES WITHOUT CC/MCC
711	TESTES PROCEDURES WITH CC/MCC
712	TESTES PROCEDURES WITHOUT CC/MCC
713	TRANSURETHRAL PROSTATECTOMY WITH CC/MCC
714	TRANSURETHRAL PROSTATECTOMY WITHOUT CC/MCC
715	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY WITH CC/MCC
717	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES EXCEPT MALIGNANCY WITH CC/MCC
718	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES EXCEPT MALIGNANCY WITHOUT CC/MCC
722	MALIGNANCY, MALE REPRODUCTIVE SYSTEM WITH MCC
723	MALIGNANCY, MALE REPRODUCTIVE SYSTEM WITH CC
728	INFLAMMATION OF THE MALE REPRODUCTIVE SYSTEM WITHOUT MCC
729	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES WITH CC/MCC
730	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES WITHOUT CC/MCC
736	UTERINE AND ADNEXA PROCEDURES FOR OVARIAN OR ADNEXAL MALIGNANCY WITH MCC
737	UTERINE AND ADNEXA PROCEDURES FOR OVARIAN OR ADNEXAL MALIGNANCY WITH CC
738	UTERINE AND ADNEXA PROCEDURES FOR OVARIAN OR ADNEXAL MALIGNANCY WITHOUT CC/MCC

DRG	DRG Description
739	UTERINE AND ADNEXA PROCEDURES FOR NON-OVARIAN AND NON-ADNEXAL MALIGNANCY WITH MCC
740	UTERINE AND ADNEXA PROCEDURES FOR NON-OVARIAN AND NON-ADNEXAL MALIGNANCY WITH CC
741	UTERINE AND ADNEXA PROCEDURES FOR NON-OVARIAN AND NON-ADNEXAL MALIGNANCY WITHOUT CC/MCC
742	UTERINE AND ADNEXA PROCEDURES FOR NON-MALIGNANCY WITH CC/MCC
743	UTERINE AND ADNEXA PROCEDURES FOR NON-MALIGNANCY WITHOUT CC/MCC
744	D&C, CONIZATION, LAPAROSCOPY AND TUBAL INTERRUPTION WITH CC/MCC
746	VAGINA, CERVIX AND VULVA PROCEDURES WITH CC/MCC
747	VAGINA, CERVIX AND VULVA PROCEDURES WITHOUT CC/MCC
748	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES
749	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES WITH CC/MCC
754	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM WITH MCC
755	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM WITH CC
756	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM WITHOUT CC/MCC
760	MENSTRUAL AND OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS WITH CC/MCC
801	SPLENECTOMY WITHOUT CC/MCC
802	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS WITH MCC
803	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS WITH CC
804	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS WITHOUT CC/MCC
808	MAJOR HEMATOLOGICAL AND IMMUNOLOGICAL DIAGNOSES EXCEPT SICKLE CELL CRISIS AND COAGULATION DISORDERS WITH MCC
809	MAJOR HEMATOLOGICAL AND IMMUNOLOGICAL DIAGNOSES EXCEPT SICKLE CELL CRISIS AND COAGULATION DISORDERS WITH CC
810	MAJOR HEMATOLOGICAL AND IMMUNOLOGICAL DIAGNOSES EXCEPT SICKLE CELL CRISIS AND COAGULATION DISORDERS WITHOUT CC/MCC
811	RED BLOOD CELL DISORDERS WITH MCC
812	RED BLOOD CELL DISORDERS WITHOUT MCC
813	COAGULATION DISORDERS
814	RETICULOENDOTHELIAL AND IMMUNITY DISORDERS WITH MCC
815	RETICULOENDOTHELIAL AND IMMUNITY DISORDERS WITH CC
816	RETICULOENDOTHELIAL AND IMMUNITY DISORDERS WITHOUT CC/MCC
820	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURES WITH MCC
821	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURES WITH CC
822	LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURES WITHOUT CC/MCC
823	LYMPHOMA AND NON-ACUTE LEUKEMIA WITH OTHER PROCEDURES WITH MCC
824	LYMPHOMA AND NON-ACUTE LEUKEMIA WITH OTHER PROCEDURES WITH CC
825	LYMPHOMA AND NON-ACUTE LEUKEMIA WITH OTHER PROCEDURES WITHOUT CC/MCC
826	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS WITH MAJOR O.R. PROCEDURES WITH MCC
827	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS WITH MAJOR O.R. PROCEDURES WITH CC
828	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS WITH MAJOR O.R. PROCEDURES WITHOUT CC/MCC
829	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS WITH OTHER PROCEDURES WITH CC/MCC
830	MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASMS WITH OTHER PROCEDURES WITHOUT CC/MCC
834	ACUTE LEUKEMIA WITHOUT MAJOR O.R. PROCEDURES WITH MCC
835	ACUTE LEUKEMIA WITHOUT MAJOR O.R. PROCEDURES WITH CC
836	ACUTE LEUKEMIA WITHOUT MAJOR O.R. PROCEDURES WITHOUT CC/MCC
837	CHEMOTHERAPY WITH ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS OR WITH HIGH DOSE CHEMOTHERAPY AGENT WITH MCC
838	CHEMOTHERAPY WITH ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS WITH CC OR HIGH DOSE CHEMOTHERAPY AGENT
839	CHEMOTHERAPY WITH ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS WITHOUT CC/MCC
840	LYMPHOMA AND NON-ACUTE LEUKEMIA WITH MCC
841	LYMPHOMA AND NON-ACUTE LEUKEMIA WITH CC
842	LYMPHOMA AND NON-ACUTE LEUKEMIA WITHOUT CC/MCC
843	OTHER MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASTIC DIAGNOSES WITH MCC
844	OTHER MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASTIC DIAGNOSES WITH CC
845	OTHER MYELOPROLIFERATIVE DISORDERS OR POORLY DIFFERENTIATED NEOPLASTIC DIAGNOSES WITHOUT CC/MCC
846	CHEMOTHERAPY WITHOUT ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS WITH MCC
847	CHEMOTHERAPY WITHOUT ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS WITH CC
853	INFECTIOUS AND PARASITIC DISEASES WITH O.R. PROCEDURES WITH MCC
854	INFECTIOUS AND PARASITIC DISEASES WITH O.R. PROCEDURES WITH CC
855	INFECTIOUS AND PARASITIC DISEASES WITH O.R. PROCEDURES WITHOUT CC/MCC
856	POSTOPERATIVE OR POST-TRAUMATIC INFECTIONS WITH O.R. PROCEDURES WITH MCC
857	POSTOPERATIVE OR POST-TRAUMATIC INFECTIONS WITH O.R. PROCEDURES WITH CC
862	POSTOPERATIVE AND POST-TRAUMATIC INFECTIONS WITH MCC
863	POSTOPERATIVE AND POST-TRAUMATIC INFECTIONS WITHOUT MCC
864	FEVER AND INFLAMMATORY CONDITIONS
866	VIRAL ILLNESS WITHOUT MCC
867	OTHER INFECTIOUS AND PARASITIC DISEASES DIAGNOSES WITH MCC
870	SEPTICEMIA OR SEVERE SEPSIS WITH MV >96 HOURS
871	SEPTICEMIA OR SEVERE SEPSIS WITHOUT MV >96 HOURS WITH MCC
872	SEPTICEMIA OR SEVERE SEPSIS WITHOUT MV >96 HOURS WITHOUT MCC
902	WOUND DEBRIDEMENTS FOR INJURIES WITH CC
907	OTHER O.R. PROCEDURES FOR INJURIES WITH MCC
908	OTHER O.R. PROCEDURES FOR INJURIES WITH CC
909	OTHER O.R. PROCEDURES FOR INJURIES WITHOUT CC/MCC
913	TRAUMATIC INJURY WITH MCC
919	COMPLICATIONS OF TREATMENT WITH MCC
920	COMPLICATIONS OF TREATMENT WITH CC
921	COMPLICATIONS OF TREATMENT WITHOUT CC/MCC
940	O.R. PROCEDURES WITH DIAGNOSES OF OTHER CONTACT WITH HEALTH SERVICES WITH CC
947	SIGNS AND SYMPTOMS WITH MCC
948	SIGNS AND SYMPTOMS WITHOUT MCC
951	OTHER FACTORS INFLUENCING HEALTH STATUS
977	HIV WITH OR WITHOUT OTHER RELATED CONDITION
981	EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITH MCC
982	EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITH CC
983	EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITHOUT CC/MCC
987	NON-EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITH MCC
988	NON-EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITH CC
989	NON-EXTENSIVE O.R. PROCEDURES UNRELATED TO PRINCIPAL DIAGNOSIS WITHOUT CC/MCC

Attachment B

Novant and Other NC Hospitals is Overcharged Cancer Drugs Amid Lobbying Battle Over Discount Program

Study: Novant and other NC hospitals overcharged cancer drugs amid lobbying battle over discount program

By **Peter Castagno** May 14, 2024

A new study carried out by the state treasurer and North Carolina State Health Plan found nonprofit hospitals overcharged for oncology drugs they purchased through a federal discount program meant to help impoverished patients.(Port City Daily photo / Johanna F. Still)

NORTH CAROLINA — A new study carried out by the state treasurer and North Carolina State Health Plan found nonprofit hospitals overcharged for oncology drugs they purchased through a federal discount program meant to help impoverished patients.

READ MORE: Novant NHRMC gets 'B' safety grade per new report

ALSO: NC treasurer supports FTC's Novant antitrust suit, argues merger would increase costs for taxpayers

The federal 340B drug-pricing program is meant to assist uninsured and low-income patients with medical expenses. It requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at a discount to eligible entities, including nonprofit hospitals providing charity care.

State treasurer Dale Folwell released the report last week, carried out in coordination with the State Health Plan, which provides healthcare to 750,000 active and retired state employees. It found hospitals collected 1.7 to 3.7 times the acquisition cost of six six common cancer drugs. State Health Plan members were charged $21,512 for melanoma drug pembrolizumab, whereas the estimated cost was $7,895.

The study detailed 340B cancer drugs provided by New Hanover Regional Medical Center, acquired by Novant in 2021, were sold to patients 70% above average sale price.

As a systemwide hospital network, Novant had the fifth highest average oncology drug markups among 15 listed providers to the State Health Plan. Cape Fear Valley Health, Atrium Health, Duke University Health System, and Vidant Health had average markups more than four times higher than the average sale price.

Brown University healthcare policy expert Christopher Whaley, who worked on the recent study, said Novant Health had a 260% profit margin on cancer drugs acquired through the discounted program.

"This is another example of why healthcare quality is so poor and healthcare costs are so high in North Carolina," Folwell told Port City Daily. "This is one of the many things these nonprofits do in the dark night that ends up gouging people who are just sick."

There is no legal requirement for hospitals to share 340B cost savings with patients or reinvest them in vulnerable communities. Last year, United States Health and Human Services secretary Xavier Becarra criticized the program's limited transparency and requested policy reforms.

The study found 340B drugs were purchased at an average 34.7% discount, and researchers argued evidence suggests hospitals made significant profits from markups to cancer patients.

"It's like this low-hanging arbitrage opportunity," Whaley told PCD.

340B policy has been the focus of major legal and lobbying battles in recent years. Pharmaceutical manufacturers argue the discounts are excessively burdensome and savings are improperly used, and have pushed to restrict drug sales to hospitals that contract with third-party pharmacies.

The majority of NC hospitals' 340B contracts are held by pharmacy chains such as Walgreens and CVS Health. Pharmaceutical manufacturers have argued some contracting pharmacies improperly share profits from discount savings with hospitals. In January, Sen. Bill Cassidy (R-LA) requested information on the Walgreens and CVS' profits from 340B contracts.

Alternatively, groups like the American Hospital Association — the country's most influential hospital trade group — have lobbied to maintain 340B benefits and opposed additional reporting requirements. In a May report, the AHA argued the 340B program is necessary to assist with growing operational costs.

Its affiliate — the North Carolina Healthcare Association — is one of the biggest lobbying groups in the state. The group, which includes Novant as a member, described the treasurer's 340B report as misleading in a recent statement. A Novant spokesperson similarly argued the study misrepresented the hospital

“The most recent claims published by the North Carolina Treasurer’s office fundamentally misrepresent the value hospitals and health systems provide to the community, dismissing the hundreds of millions of dollars of investment we provide each year and overlooking the role of pharmaceutical companies and health plans in care delivery.”

In an April interview with 340B Insight podcast, Novant pharmacy business director Matt Webber said the hospital network uses a multidisciplinary team — finance and data analytics experts, accountants, and pharmaceutical specialists — to optimize compliance with the program’s rules.

Novant’s system-wide clinical database is supplied by Vizient, a company that provides healthcare services including 340B consulting. Vizient is also the biggest of the three largest “group purchasing organizations,” or GPOs, which handle bulk purchasing of medical supplies for 90% of the country’s health systems. GPOs provide contracts to hospitals to gain discounts on healthcare products, as they use aggregate purchasing volume as leverage in negotiations with vendors.

The Senate Finance Committee has recently criticized GPO control of the generic drug market, including cancer drugs, for contributing to shortages. Earlier this month, Senate Finance Committee Chair Ron Wyden (D-Oregon) described GPOs as “monopolistic middlemen” causing market disruptions and driving up costs.

Novant CEO Carl Armato is on Vizient’s board of directors and the companies are in a group purchasing organization together, according to a Novant spokesperson. Vizient’s contract portfolio constitutes more than $130 billion in annual purchasing volume.

Apexus LLC, which is a wholly owned subsidiary of Vizient, has an exclusive contract with the Health Resources and Services Administration to administer the 340B program and negotiate sub-ceiling prices — prices below the HRSA’s statutory 340B costs — with pharmaceutical companies.

Port City Daily asked Vizient for information about Apexus’ finances, including if Apexus is paid for its role negotiating 340B prices with individual manufacturers, but was told the companies did not have a comment on the inquiry.

Vizient cited 340B policy as a top focus in its $270,000 federal lobbying disclosure for the first quarter of 2024. This includes lobbying on the “SUSTAIN 340B Act,” a bipartisan discussion draft submitted by six senators in February. It puts new transparency requirements on hospitals to report how they use 340B savings and mandates pharmaceutical companies sell drugs to eligible entities at 340B prices without conditions.

Vizient wrote in an April letter regarding the bill’s draft that it supported provisions that would prevent manufacturers from refusing or placing conditions on 340B drug deliveries. However, it opposed putting new requirements on how 340B recipients use savings from discounted drugs.

“Policies that narrow how 340B Program savings could be used, such as directing them solely to the provision of pharmaceuticals to vulnerable populations, would result in fewer services being provided more broadly, including in underserved communities,” Vizient wrote in the letter.

Sayeh Nikpay, a University of Minnesota health policy researcher who contributed to the recent State Health Plan study, told PCD there is evidence 340B status incentivizes hospitals to carry out acquisitions. She cited a 2018 New England Journal of Medicine study associating the 340B program with hospital-physician consolidation in hematology-oncology, but found hospitals’ financial gains from the program did not improve care among low-income patients.

Novant has expanded rapidly in recent years, although its recent attempt to acquire two hospitals in Iredell County hit a roadblock after the Federal Trade Commission filed an antitrust suit to block the purchase in January.

The state treasurer submitted a brief in support of the FTC’s motion last month, arguing the consolidation would increase costs for taxpayers contributing to the state health plan. The treasurer and State Health Plan have worked together on past studies raising concerns about inadequate oversight of the state’s nonprofit hospitals to ensure charitable spending justifies tax exemptions.

“When it comes to these multi-billion dollar corporations that are gouging people and disguising themselves as nonprofits, we’re not going to look the other way,” Folwell said.

Tips or comments? Email journalist Peter Castagno at peter@localdailymedia.com.

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