**Novant Health Forsyth Medical Center**
**Comments in Opposition to**
**Alliance Healthcare Services, LLC's Application**
**to Acquire a Mobile PET/CT Unit**
**Pursuant to the 2021 Need Determination**
**November 1, 2021 CON Review Cycle**

## INTRODUCTION

In accordance with N.C. Gen. Stat. § 131E-185(a)(1), Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center ("NHFMC") submits the following comments related to competing applications to acquire a mobile PET/CT unit pursuant to the need determination as published in the 2021 State Medical Facilities Plan ("SMFP"). To facilitate the Agency's review of these comments, NHFMC has organized its discussion by issue, citing the general CON statutory review criteria and specific regulatory criteria and standards. NHFMC also provides a comparative analysis of all applications.

Two applicants have filed Certificate of Need ("CON") applications in response to the identified need. These are Project I.D. No. G-012142-21 submitted by NHFMC, and Project I.D. No. G-012156-21, submitted by Alliance Healthcare Services, Inc. ("Alliance").

The identified areas of non-conformity of Alliance along with the comparative analysis set forth below reveal that NHFMC is the most effective applicant in this review, and as such, should be approved.

## OVERVIEW

As the Agency will recall, 2018 was the last time there was a statewide need determination for a mobile PET scanner. Three applicants applied to meet this need determination. The Agency approved the application submitted by InSight and disapproved the competing applications filed by Novant and Mobile Imaging Partners of North Carolina, LLC ("MIPNC"), a joint venture composed of Alliance and UNC Rockingham. Novant and Alliance appealed the Agency's decision. Novant dismissed its case with prejudice but Alliance pursued its appeal to conclusion. The ALJ issued a Final Decision upholding the Agency's decision. Alliance appealed the Final Decision to the North Carolina Court of Appeals, which affirmed the ALJ's decision upholding the award to InSight. One of the main issues in the case was whether InSight's application demonstrated that it proposed to serve two or more host sites, as a mobile PET scanner is required to do. The Court of Appeals recounts that Alliance undertook efforts to encourage InSight's two host sites to rescind their support for InSight's CON application, going so far as to prepare draft recission letters. One host site, UNC Caldwell, acquiesced to Alliance's demand and signed the recission letter. "Respondents set forth ample evidence before the DHHS and the ALJ showing any recission of support was the result of Petitioner's anti-competitive behavior to ensure it was awarded the CON." *Mobile Imaging Partners of N.C., LLC v. NCDHHS*, No. COA20-605 (July 6, 2021) at ¶ 22 (copy attached).

Having failed to convince the Court of Appeals to overturn the 2018 award to InSight, Alliance has submitted another application in 2021, once more seeking to further its market dominance in mobile PET imaging in North Carolina. If its 2021 application is approved, Alliance will have three mobile PET/CT scanners whereas Novant and InSight have one mobile PET scanner each. As is true for most healthcare services, competition in mobile PET imaging helps improve quality, cost and access, which are fundamental tenets of the CON Law. In this review, the Agency has another opportunity to enhance competition for the benefit of North Carolina's citizens.

The 2021 Alliance project is focused exclusively on meeting the needs of hospitals in the UNC Health system. While there is nothing wrong with this exclusivity, Alliance has failed to document the need for several of the host sites within its proposed route. This application is much like the 2018 application filed by MIPNC. In fact, Alliance proposes to serve many of the same routes as the 2018 application including host sites in Rockingham, Henderson, Wayne, and Caldwell Counties. MIPNC's application was correctly denied in 2019, and, likewise, Alliance's current application should also be denied.

In addition to repeating many of the same host sites in the 2018 application, Alliance now claims that its project will alleviate capacity constraints at UNC Hospitals at Chapel Hill ("UNC – Chapel Hill"). Alliance fails to provide sufficient documentation that UNC – Chapel Hill has capacity constraints based on its reported three underutilized fixed PET units. Instead, Alliance's project fails to show need and represents an unnecessary duplication of services.

In addition, Alliance's application appears to understate and under-project staffing, salaries and other expenses in an effort to appear comparatively superior. Alliance's understated staffing and expenses are inconsistent with quality care because they demonstrate insufficient resources to support the project. Alliance's application is non-conforming with numerous review criteria and should be denied.

## NON-CONFORMITY WITH REVIEW CRITERIA

### Criterion (1)

The Alliance application is non-conforming with Criterion (1) because it does not promote quality and safety, promote equitable access, or maximize healthcare value for resources expended as required by Policy GEN-3: Basic Principles as discussed below. In addition, for the multiple reasons discussed in detail under Criteria (3), (4), (5), (6), (7), (13c), and (18a), Alliance should be found non-conforming with Criterion (1).

*Safety and Quality*

As will be shown, Alliance does not include sufficient staffing, particularly in terms of clinical FTEs to ensure that quality PET services will be offered through the proposed mobile unit. In addition, by proposing a smaller, low-end mobile PET unit without many of the clinical quality

features available today, Alliance is sacrificing quality for so-called low costs. This is a disservice to the citizens of North Carolina who deserve better than what Alliance proposes.[1]

Equitable Access

Alliance proposes to expand access to UNC affiliated hospitals; however, Alliance has not demonstrated that all site locations need additional capacity or expanded geographic access. As will be discussed, UNC – Chapel Hill has available capacity on its existing multiple PET units as shown in the 2021 SMFP and Proposed 2022 SMFP. Alliance does not demonstrate why UNC – Chapel Hill needs additional capacity given the publicly available data on existing capacity. Moreover, Rockingham County is already served by the Alliance Mobile I unit at Annie Penn Hospital in Reidsville. Alliance has not explained how this small county (92,000 residents per CON pg. 58 with a declining population) can justify a second PET provider and has not taken into consideration any impact on Annie Penn Hospital in its projected overall utilization. The only truly new host site from a geographic perspective is UNC Chatham Hospital, a rural Critical Access Hospital, with an average daily census of six patients and no oncologists on staff. Alliance has failed to demonstrate how UNC Chatham can support a PET service. For these reasons, and additional factors discussed below, Alliance's project does not expand equitable access.

Maximum Healthcare Value

Alliance proposes a widespread, non-contiguous, and, most importantly, inefficient service area for one mobile PET/CT unit. Alliance's mobile route focuses on serving geographically dispersed UNC affiliates instead of its most highly utilized host sites. As a result, the proposed route is inefficient, spanning from Western North Carolina to east of Raleigh – around 350 miles. Moreover, Alliance fails to document the need for PET capacity at each of its proposed mobile sites. As discussed in detail in Criterion (3), Alliance fails to document the need for and utilization of several additional proposed sites. For these reasons, Alliance's project does not maximize healthcare value.

Based on these issues, as well as any other issues the Agency may discern, Alliance's application is not consistent with Policy GEN-3 and should be found non-conforming with Criterion (1).

**Criterion (3)**

Alliance fails to demonstrate the need for its proposed project as required by Criterion (3) for numerous reasons, including unsupported and unrealistic utilization projections, an inefficient and unjustified route, and questionable documentation.

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[1] Alliance's proposed scanner – the Siemens Biograph Horizon – does not have continuous bed motion capabilities, has smaller bores (not suitable for larger patients or patients prone to claustrophobia), and shorter tunnel lengths (not suitable for accommodating additional rings or longer lengths).

*Alliance's Proposed Sites and Route Are Inefficient and Unsupported*

Alliance's proposed route spans from Henderson County in western North Carolina to Wayne County in eastern North Carolina, over 350 miles away. Such a large service area most certainly increases transportation costs and wear and tear on the equipment. The unit will be spending more time traversing North Carolina's highways than it will spend actually serving patients. In order to cover this area, Alliance must operate 12 hours a day/6 days a week, serving more than one site a day and traveling late at night across the state. Patients would have to fast for hours to accommodate a late evening scan.[2] In other words, the patients must meet the machine's schedule, when the exact opposite should be true. Further, any unforeseen circumstance that may arise could easily disrupt such a complicated schedule. For instance, inclement weather or an accident on a major highway could pose a significant scheduling issue. A more reasonable service area would allow for flexibility to adjust when such unforeseen circumstances occur. The aggressive travel route for the proposed scanner makes it more likely that the scanner and the coach will be down for repairs on a frequent basis.

Alliance proposes to serve three existing host sites: Margaret R. Pardee Hospital, Caldwell Memorial Hospital, and Wayne Memorial Hospital. These sites are located more than 350 miles apart from Hendersonville to Goldsboro. Alliance has not provided any evidence of capacity constraints at these facilities to justify additional days of service at these sites. Moreover, Alliance has not explained what will happen to the additional days of service on its exiting Alliance II mobile unit once Southeastern Regional Medical Center opens its approved fixed PET unit.[3] Alliance does not acknowledge that this will provide for extra capacity to serve other sites, including Wayne Memorial Hospital. It is unclear why Alliance would choose these three distant sites as the starting point for its proposed new mobile PET route.

Furthermore, Alliance has not demonstrated that its new sites are needed. Alliance proposes to serve rural Rockingham and Chatham Counties; however, there is no evidence that these areas do not have access to existing PET services. Annie Penn Hospital, served by the Alliance I mobile, already serves Rockingham County. UNC Chatham Hospital is a rural Critical Access Hospital with an ADC of six patients and no oncology program, It cannot support a mobile PET service. Moreover, this location is within 30 to 40 miles of existing PET units operated by UNC – Chapel Hill on its main campus and Biomedical Research Imaging Center adjacent to its campus. These host locations do not improve access to care.

Finally, Alliance's proposed sites in Orange County, UNC Hospital – Hillsborough and UNC Eastowne Medical Office Building, are simply redundant with the capacity on UNC's nearby main campus as will be discussed in detail below. Alliance has not documented that UNC has capacity constraints that need to be addressed through the proposed mobile unit. In conclusion, Alliance proposes three existing and four new sites without any documentation of capacity constraints or need for PET capacity at any of these sites.

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[2] Some scans require the patient to fast for a period of time beforehand. The later in the day a scan is given, the longer a patient must fast.

[3] See Alliance CON page 65 and 80. Southeastern Regional Medical Center will begin operating a fixed PET scanner sometime in 2022 and will be removed from Alliance II's route. Alliance does not explain where Southeastern Regional's days of service will be reallocated.

*Alliance's Projected Utilization by Host Site is Unreasonable*

There are flaws with the projection for each host site as discussed in detail below. Most obviously, however, Alliance uses the same 12 percent growth rate for the utilization of each site regardless of any historical experience, population growth rates, or other factors that would impact PET demand. This is wholly unreasonable give the wide variety of host side locations.

Margaret R. Pardee Hospital

Margaret R. Pardee Hospital ("Pardee") located in Henderson County is the largest host site by volume projected by Alliance. Pardee has been served by Alliance I and has had steady growth in volume. However, Alliance does not indicate how many days of service this site has or provide any tangible evidence of capacity constraints. Alliance I also serves Advent Health Hendersonville (f.k.a. Park Ridge Hospital) in the same county, which has a lower scan volume. Alliance does not discuss whether it can share days between these two sites located just six miles apart in the same small county or whether any other alternatives exist to serve Pardee if it needs additional capacity. The absence of discussion does not mean the issue should not be considered; it simply means Alliance chose not to discuss the issue. The reason for not discussing the issue is clear: it does not support Alliance's case.

Over 64 percent of Henderson County residents are already served within the county. (See CON application, Exhibit C page 87.) The vast majority of patients who leave the area are going to Mission Hospital in adjacent, nearby Buncombe County. Alliance ignores the fact that the Agency recently approved additional fixed PET capacity in HSA I in Project I.D. No. B-12059-21. The approved applicant, American Oncology Partners, proposes to locate its scanner in Buncombe County.[4] Redirection of patient volume is unlikely given the approval of additional fixed PET capacity in Buncombe County. Alliance's projections for Pardee are unreasonable and unsupported.

Finally, Alliance's projections for Pardee are also inconsistent. Pages 64, 79, and 119 show 650, 729, and 816 scans for the first three years of operation 2023-2025, respectively. Yet page 45 shows 639, 716, and 802 scans per year for the first three years of operation, respectively. All time periods are reported CY 2023 through CY 2025.

Alliance's projections for Pardee are unreasonable and unsupported.

Caldwell Memorial Hospital

Liked Pardee, Caldwell Memorial Hospital ("Caldwell") is an existing host site served by Alliance I. Caldwell County is a mostly rural county, projected to grow just 2.34 percent between 2023 and 2025, much slower than the statewide rate. (See CON application, page 58.) Since FFY 2015, Caldwell has never provided more than 200 scans. Alliance does not state how many days per week it provides service to this site or provide any tangible evidence of capacity constraints. Yet,

[4] Mission also applied for meet the need determination for additional fixed PET capacity in HSA I. Mission proposed to locate its PET scanner in Buncombe County. Mission appealed American Oncology Partners' approval in Case No. 21 DHR 4359. Since both applicants proposed to locate their equipment in Buncombe County, the outcome of the litigation will not change the fact that additional PET capacity will be added in Buncombe County.

Alliance projects sustained 12 percent projected growth in PET volume for this site. This is inherently unreasonable and unsupported.

Over 50 percent of Caldwell County residents receive PET services in their home county. (See CON application, Exhibit C page 87.) The majority of patients leaving the area are going to UNC Health Blue Ridge Hospital ("UNC – Blue Ridge"), which is already served by Alliance I. The only way to project an increase of over 100 scans in three years is to redirect outmigration as implied on CON Exhibit C page 87. However, Alliance has not shown the impact of any shift from UNC Blue Ridge to Caldwell in its projections for Alliance I.

Finally, Alliance's projections for Caldwell are also inconsistent. Page 41 shows 395 PET patients for FFY 2020 at Caldwell yet page 80 shows just 183 PET scans. Pages 64, 79, and 119 show 260, 291, and 326 scans for the first three years of operation 2023-2025, respectively. Yet page 46 shows 254, 284, and 318 scan per year for the first three years of operation, respectively. All time periods are reported CY 2023 through CY 2025.

Alliance's projections for Caldwell are unreasonable and unsupported.

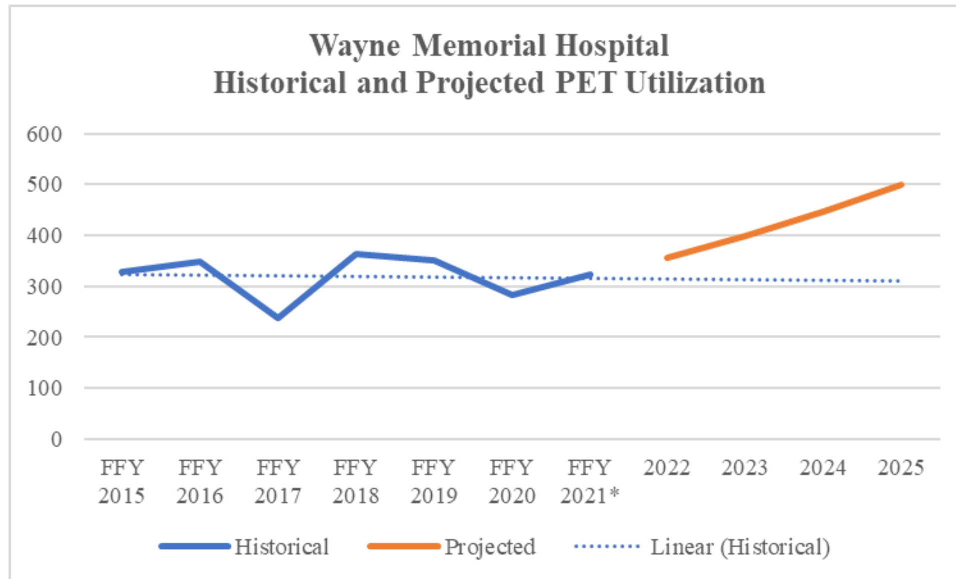
Wayne Memorial Hospital

Wayne Memorial Hospital ("Wayne") is currently served by Alliance II. Wayne County is a predominantly rural county whose population is projected to grow just 1.5 percent between 2020 and 2025, much slower than the statewide rate. (See CON application, page 58.) Since FFY 2015, Wayne has never provided more than 364 scans. Alliance does not state how many days per week it provides service to Wayne or provide any tangible evidence of capacity constraints. Wayne's actual PET scan growth rate from FFY 2015 to FFY 2019 has been just 1.6% as shown below.[5] Yet, Alliance projects a sustained 12 percent projected growth in PET volume. There is no reasonable basis provided for such a dramatically high growth rate. On page 64, Alliance picks the clearly anomalous FFY 2017 to imply a 7.9% historical growth rate for Wayne. This is obviously inappropriate given the last five-year CAGR of 1.6%

| | **2017 SMFP FFY 2015** | **2018 SMFP FFY 2016** | **2019 SMFP FFY 2017** | **2020 SMFP FFY 2018** | **2021 SMFP FFY 2019** | **CAGR%** |
|---|---|---|---|---|---|---|
| Wayne Memorial Hospital | 329 | 348 | 238 | 364 | 350 | 1.6% |

The projections for Wayne Memorial Hospital are unreasonable and unsupported as graphically depicted below:

[5] FFY 2020 actually shows a decline, but this may potentially be due to COVID-19.




**Annualized*

The only other way to achieve such significant growth rates is to redirect outmigration, although Alliance does not project any change in patient origin. In FFY 2020, 62 patients traveled from Wayne County to UNC – Chapel Hill for PET scans. If these patients are to shift to the Wayne host site, this would need to be subtracted from the base of patients Alliance projects to shift to UNC – Hillsborough and UNC – Eastowne MOB. Patient origin data shows that the majority of the remaining outmigration is to Pitt or Wake County for patients who are choosing a health system other than UNC, which is unlikely to change due to patients' affiliation with an oncologist.

Finally, Alliance's projections for Wayne are also inconsistent. Pages 64, 79, and 119 show 398, 446, and 499 scans for the first three years of operation 2023-2025, respectively. Yet page 46 shows 415, 465, and 521 scan per year for the first three years of operation, respectively. All time periods are reported CY 2023 through CY 2025.

Alliance's projections for Wayne are reasonable and unsupported.

<u>UNC – Chapel Hill and Projected New Host Sites</u>
The new sites proposed by Alliance all appear to be focused on redistributing patient volume from UNC – Chapel Hill. However, Alliance fails the fundamental test of demonstrating that UNC – Chapel Hill cannot serve this patient volume. In fact, it appears UNC – Chapel Hill has significant excess capacity. The 2021 and Proposed 2022 SMFPs show UNC – Chapel Hill operating at 66.98 percent and 61.87 percent of capacity, respectively. Alliance does not provide any documentation to suggest that this is not a true and accurate reflection of UNC's available fixed PET capacity.

Alliance does not provide any discussion or analysis of the full extent of UNC – Chapel Hill's available capacity. The SMFPs show an inventory of two fixed PETs units. In fact, UNC – Chapel Hill has three fixed PET units on its license as reported on its 2021 LRA excerpted below:

2021 Renewal Application for Hospital:
**University of North Carolina Hospitals**

License No: **H0157**
Facility ID: **923517**

All responses should pertain to **October 1, 2019 through September 30, 2020**.

**g. Positron Emission Tomography (PET). Campus** – ***if multiple sites:*** Medical Center

| | Number of Units | Number of Procedures* | | |
|---|---|---|---|---|
| | | Inpatient | Outpatient | Total |
| Dedicated Fixed PET Scanner | 1 | 507 | 3,205 | 3,712 |
| Mobile PET Scanner | 0 | — | — | — |
| PET pursuant to Policy AC-3 | 1 | 130 | 852 | 982 |
| PET/MR Other PET Scanners u~~sed for Human Research onl~~y | | | | |

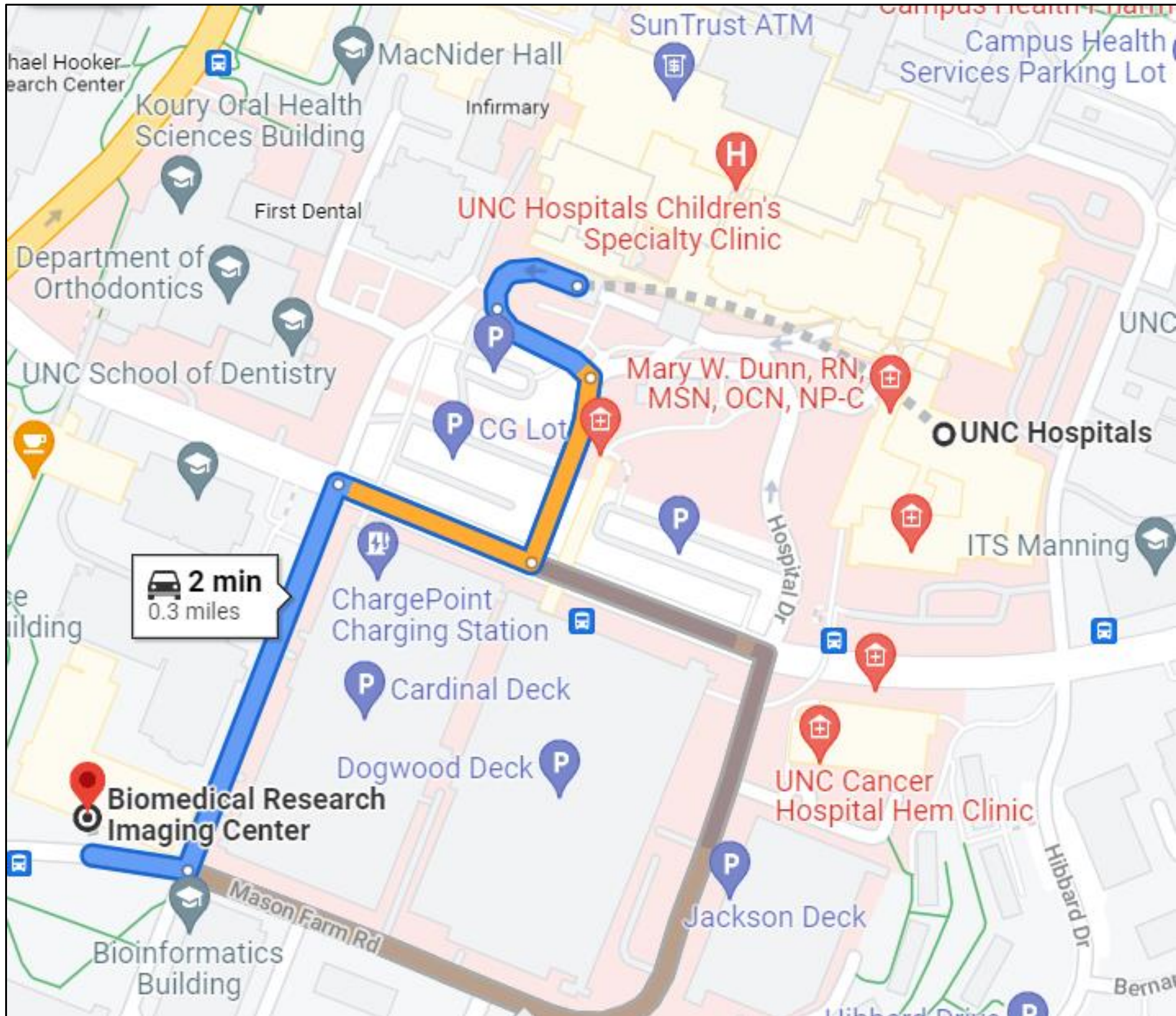
* **PET procedure** means a single discrete study of one patient involving one or more PET scans. PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. **The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 31.**

**For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.**

CON Project ID numbers for all non-grandfathered fixed PET scanners on this campus: 1. J - 6171 - 99

2. J - 7100 - 04 ; 3. J - 10016 - 12 PET/MR

UNC – Chapel Hill has two dedicated fixed units on its campus including one approved pursuant to Policy AC-3. While this unit does not officially count in the SMFP need calculation, it is clearly available to serve patients without any restrictions and provided 982 scans in FFY 2020 (just 32.7 percent of capacity). Moreover, UNC – Chapel Hill has a PET/MR unit for which it received approval to provide clinical services at the Biomedical Research Imaging Center ("BRIC") location under Project ID J-10016-12. This location is adjacent to the UNC Hospitals' campus and in close proximity to the UNC Cancer Hospital Hematology Clinic as shown below:




Alliance does not explain why patients are not being served on the BRIC PET unit if UNC – Chapel Hill is facing such capacity constraints. The Agency Findings approving the BRIC PET/MR state:

> .3702(b)(3)(B) This rule states *"(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, ...(3) Documentation that the facility will: ... (B) provide scheduled hours of operation for the PET scanner of a minimum of 60 hours per week, except for mobile scanners."*
>
> -C- In Section II.8(3)(B), page 27, the applicant states, *"PET services are available at UNC Hospitals 24 hours a day, 7 days a week. Scans can be scheduled Monday through Friday from 6:00 am until 6:00 pm. Emergency and after-hours coverage is provided on an on-call basis. The PET MR scanner would be available for clinical use between the laboratory's hours of 7:30 am and 4:00 pm, Monday through Friday.*

*Project ID J-10016-12, page 25*

Additionally, in its June 2021 application, UNC provides the following on page 22:

"Of note, the PET/MR, which was awarded pursuant to Project ID # J-10016-12, allows UNC to purchase services from an existing research PET/MR at the UNC School of Medicine Biomedical Research Imaging Center for use for clinical patient care. *Utilization of the PET/MR allows UNC Hospitals to offer to clinical patients who can benefit from this advanced imaging, but do not "qualify" for a specific research study, the ability to utilize this technology as part of the identification and treatment of their diseases.*" (Emphasis added.)

It is clear that the PET/MR is available as additional imaging capacity. Alliance does not provide any information regarding why UNC is not using this PET/MR as indicated. When all available PET capacity is considered at UNC, the three existing units are operating at just 52.5 percent of available capacity as shown below:

**UNC - Chapel Hill PET Utilization and Capacity**

| PET Unit: | LRA: 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|
| Dedicated Fixed | 3,313 | 3,513 | 4,019 | 3,712 |
| Policy AC-3 | 839 | 737 | 879 | 982 |
| Other (PET/MR) - BRIC | 45 | 28 | 41 | - |
| Total PET Scans | 4,197 | 4,278 | 4,939 | 4,694 |
| Total Units | 3 | 3 | 3 | 3 |
| Scans per Unit | 1,399 | 1,426 | 1,646 | 1,565 |
| ***Percent of Capacity*** | ***46.6%*** | ***47.5%*** | ***54.9%*** | ***52.2%*** |

In addition, UNC-Chapel Hill applied for the fixed PET scanner available in the Health Service Area IV Review, Project I.D. No. J-012089-21. Alliance did not discuss this application at all. The Agency denied UNC's application in late November 2021. The fact that this application was denied undercuts Alliance's argument that host sites (Hillsborough and Easttowne) in close proximity to UNC Chapel Hill's campus need mobile PET services. UNC Chapel Hill has capacity to meet whatever need for PET exists at these sites.

Alliance failed to demonstrate the need for the new UNC affiliated hosts sites, taking into consideration the available capacity at UNC – Chapel Hill and that any shift in volume to the new host sites will leave even more apparently unused capacity at UNC – Chapel Hill as will be discussed below.

UNC Rockingham Hospital (New)

UNC Rockingham Hospital ("Rockingham") is a proposed new site in Rockingham County. Rockingham County's population is projected to decline by 0.36 percent between 2020 and 2025. (See CON application, page 58.) Alliance fails to discuss that Annie Penn Hospital ("Annie Penn"), located just 11 miles and 10 minutes from Rockingham, served by Alliance I since FFY 2019 is already serving Rockingham County. Alliance projects continued growth for Annie Penn in addition to new volume at UNC Rockingham.

Without redirection from other providers, 250 new PET scans at Rockingham will not just simply materialize. In FFY 2020, just 40 patients traveled from Rockingham County to UNC – Chapel Hill. (See 2021 LRA.) If these patients are to shift to the new Rockingham host site, this would need to be subtracted from the base of patients Alliance projects to shift to UNC – Hillsborough and UNC – Eastowne MOB. Moreover, any patient volume shifted from UNC – Chapel will result in even greater underutilization of its three existing PET units. Alliance did not take this into consideration. Patient origin data shows that the majority of the remaining outmigration is to Guilford or Forsyth County for patients who are choosing a health system other than UNC, which is unlikely to change. There is no other quantitative basis for the projected initial volume at Rockingham or the 12 percent growth in year 1 and year 2.

Alliance's projections for Rockingham are unreasonable and unsupported.

UNC Chatham Hospital (New)

UNC Chatham Hospital ("Chatham") is a proposed new site in rural Chatham County. Chatham is a Critical Access Hospital with 25 beds, which had an average daily census of less than six patients for FFY2020. Chatham County's population is projected to be 85,000 in 2025. (See CON application, page 58.) According to its website, UNC – Chatham does not have any oncologists on its medical staff who would make referrals to the proposed PET unit. Patients do not self-refer for PET scans so the lack of an oncologist on Chatham's medical staff is a significant issue.

NHFMC fully supports local access to PET services and easing travel burdens for cancer patients. But the CON Law still requires projections that are reasonable and supported, and Alliance's projections are not reasonable and supported. In 2020, 321 patients from Chatham County received PET scans. Of these, 241 traveled to UNC – Chapel Hill. In order to project 251 scans at the mobile site, all volume from UNC – Chapel Hill would need to be redirected to Chatham, and there would also need to be additional growth. No support exists for the shift in patients from UNC – Chapel Hill to UNC Chatham. It is unreasonable to forecast that all PET scans now done at UNC – Chapel Hill on Chatham County residents would shift to Chatham. Moreover, if these patients are to shift to the new Chatham host site, this volume would need to be subtracted from the base of patients Alliance projects to shift to UNC – Hillsborough and UNC – Eastowne MOB. Alliance did not take this into consideration. Further, any patient volume shifted from UNC – Chapel Hill will result in even greater underutilization of its three existing PET units.

There is no other quantitative basis for the projected initial volume at UNC Chatham nor the 12 percent growth in year 1 and year 2. In fact, the number of Chatham County residents receiving PET scans at UNC – Chapel Hill has been declining since FY 2017 as shown below. Even setting aside the potential impact of COVID-19, Chatham County scans decreased by 4.1 percent between FY 2017 and FY 2019. There is no justification for a projected 12 percent annual growth rate.

**UNC PET Scans from Chatham County**

| FY 2017 | FY 2018 | FY 2019 | FY 2020 | CAGR 2017-2020 | CAGR 2017-2019 |
|---|---|---|---|---|---|
| 287 | 266 | 264 | 241 | -5.7% | -4.1% |

*Source: UNC LRAs*

Alliance's projections for Chatham are unreasonable and unsupported.

UNC Hospital – Hillsborough and UNC Eastowne Medical Office Building
UNC Hospital – Hillsborough ("Hillsborough") and UNC Eastowne Medical Office Building ("Eastowne") host sites are both located in Orange County in reasonable proximity to UNC – Chapel Hill's three existing PET units. According to www.googlemaps.com, Eastowne is 5.5 miles from the main campus and Hillsborough is 11.1 miles from the main campus.

There is no quantitative basis for the projected utilization at Hillsborough and Eastowne other than a statement of the estimated volume per day for each host site. (See CON application, page 139.) Alliance generally relies on claims of growth in UNC referrals and recruitment, which does not translate into any specific volume of scans. Like Rockingham and Chatham, there is no other quantitative basis for the projected initial volume at Hillsborough or the 12 percent growth in year 1 and year 2. Such volume would undoubtedly shift from UNC – Chapel Hill; however, UNC – Chapel Hill has only experienced a CAGR of 3.8 percent from FFY 2017 to FFY 2020 based on LRA data. This hardly supports a 12 percent growth rate for the projected sites that will purportedly offload its volume. Finally, to the extent that Rockingham and Chatham will shift volume from UNC – Chapel Hill, this has not been considered in Alliance's projections for Hillsborough and Eastown, which will serve the same base of patients. Further, any patient volume shifted from UNC – Chapel Hill will result in even greater underutilization of its three existing PET units.

Alliance's projections for Hillsborough and Eastowne are unreasonable and unsupported.

*Cardiac PET Services*

Alliance states several places in its application that it provides cardiac PET services, which require Rubidium as the radioisotope. This radioisotope is required in order to assess myocardial perfusion. It is unclear whether any existing or proposed host site has a Rubidium generator. Moreover, the letter from PETNET, the radiopharmaceutical provider, does not indicate that it does or will provide Rubidium. It is unclear whether Alliance actual does or will provide this service. No cardiac scans have been identified in the application either historically or on a projected basis.

*Alliance's Projections for its Existing Mobile Units are Unreasonable*

On pages 80, 136 and 137 of its application, Alliance projects the utilization of its existing PET units following the implementation of the proposed project. There are multiple flaws with Alliance's projections for its existing Alliance I and Alliance II units that render the analysis unreasonable and unsupported.

- First, and most obvious, on pages 80 and 137 Alliance fails to remove Wayne Memorial from its projections for Alliance II. Thus, the utilization of Wayne Memorial is double counted in both the new unit projections and Alliance II projections.

- Next, Alliance's approach to projecting utilization is flawed. Alliance picks an arbitrarily low utilization year (FFY 2015 / SMFP 2017) from its operations six years ago and uses this as the starting point to calculate a cumulative CAGR of 4.28 percent across both units and all host sites. (See page 135.) This six-year-old starting point is unreasonable and outdated for several reasons.

    - The mobile route for Alliance I in FFY 2015 included multiple Novant Health host sites that were all eliminated in FFY 2017 when NHFMC received approval for its own mobile unit.
    - The largest single host site in FFY 2015 was Duke Raleigh Hospital with almost 700 patients. This site grew to over 1,100 scans per year before approval of its fixed PET unit. Alliance stopped serving this site in FY 2019.
    - These two major changes in the utilization and routes for Alliance I and Alliance II confound the historical trend from FFY 2015, making this an unreasonable starting point for a growth rate.

- Using a more recent trend in overall utilization for the Alliance mobiles demonstrates at best a flat utilization trend as shown below.

| Unit | 2020 SMFP FFY 2018 | 2021 SMFP FFY 2019 | 2022 SMFP FFY 2020 | FFY 2021 Annualized | % CAGR FY 2018-2021 | % CAGR FY 2019-2021 |
|---|---|---|---|---|---|---|
| Alliance I | 3,363 | 3,716 | 3,959 | 4,436 | 9.7% | 9.3% |
| Alliance II | 4,363 | 3,975 | 3,299 | 3,478 | -7.3% | -6.5% |
| Total | 7,726 | 7,691 | 7,258 | 7,913 | 0.8% | 1.4% |

**FFY 2021 annualized is from CON pages 136-137.*

- Finally, Alliance uses the same overall growth rate for all host sites regardless of their historical growth trend. For example, Randolph Hospital, Watauga Medical Center, West Care Health System (f.k.a. Harris Regional), UNC Lenoir Healthcare, and Onslow Memorial Hospital all experienced significant declines in utilization during the time period used by Alliance for its growth rate as shown below. Yet, each of these sites were projected to increase at 4 percent annually going forward with no explanation.

| | 2017 SMFP FFY 2015 | 2018 SMFP FFY 2016 | 2019 SMFP FFY 2017 | 2020 SMFP FFY 2018 | 2021 SMFP FFY 2019 | CAGR% |
|---|---|---|---|---|---|---|
| Randolph Hospital | 179 | 151 | 135 | 126 | 132 | -7.3% |
| Watauga Medical Center | 210 | 226 | 117 | 121 | 165 | -5.9% |
| WestCare Health System (Harris | 305 | 283 | 263 | 237 | 260 | -3.9% |
| The Outer Banks Hospital | 117 | 141 | 159 | 152 | 110 | -1.5% |
| Wilson Medical Center | 430 | 444 | 407 | 378 | 375 | -3.4% |

*Source: SMFPs.*

For these reasons, Alliance's projections for its existing mobile units are unreasonable and unsupported.

In conclusion, the numerous flaws and unsupported projections contained in Alliance's need analysis and utilization projections, plus any additional reasons the Agency may discern, should result in a finding of non-conformity with Criterion (3).

**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."*

As previously established, Alliance proposes to serve only one site that adds PET services to a county where none exists today, Chatham County. However, Chatham County's rural Critical Access Hospital is too small to support the PET/CT volume Alliance claims. Moreover, the plan to offload UNC's volume to the new hosts sites is duplicative with the significant excess capacity this facility has both on campus and at its BRIC location on the edge of campus. Alliance did not address UNC – Chapel Hill's apparent significant available and unused capacity as an alternative. The proposed sites are not the most effective alternative to expand access to PET services in North Carolina.

<u>For these reasons, in addition to any other reasons the Agency may discern, Alliance should be found non-conforming with Criterion (4).</u>

**Criterion (5)**

Alliance's utilization projections are not based on reasonable assumptions for multiple proposed sites as discussed under Criterion (3). This in turn raises concerns about the reasonability of Alliance's financial projections. In addition, there are other reasons why the Alliance application should be found non-conforming with Criterion (5).

*Revenue per Scan is Understated*

Alliance projects $940 per scan without any inflation across the projected first three years of operation. It is impossible to determine if this is reasonable given that the "fee" section of the sample host site agreement is left blank. The sample host site agreement on page 4 does indicate that fees paid to Alliance may be increased by 10 percent during the term of the agreement. **See Alliance Exhibit C.8 page 149.** At $940 per scan, this is less that the charge of $952 per scan in the 2018 application filed by Alliance affiliate MIPNC. It is not reasonable to project that Alliance's fees have actually declined since 2018 and that there will be no inflation of fees/charges going forward.

Further, Alliance does not appear to consider that Medicare and Medicaid reimbursement rates have declined since 2018. If Alliance plans to serve underserved populations, it should be serving a higher rate of Medicare and Medicaid patients, which equates to lower reimbursement rates, and lower revenue per scan.

*Understated Staffing and Salaries*

As will be described in detail under Criterion (7) below, Alliance has understated the FTE associated with the truck driver position given the number of sites and distant locations for which Alliance has planned service. Alliance has also understated its FTEs for technologists. From an operational standpoint, it is most efficient to operate at a ratio of 1 technologist to 4 patients. In addition, Alliance's salaries are understated. Each position is actually lower than projected by Alliance affiliate MIPNC in 2018 without accounting for inflation. If salaries from the 2018 application were inflated at 2.5 percent annually and the appropriate level of staffing included, Alliance would have approximately $350,000 in additional expense. Again, Alliance has understated its costs and provided no rationale for the assumption.

Based on these issues, plus any additional issues the Agency may discern, Alliance's application should be found non-conforming with Criterion (5).

**Criterion (6)**

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

As discussed previously, Alliance's projected utilization is unsupported particularly for host sites that have previously experienced little growth or even a decline in utilization. Alliance proposes to add capacity to rural Rockingham County where there is already an existing host site Alliance serves with one of its mobile units. Adding more capacity to these rural sites, as proposed by Alliance, is unnecessary and duplicative because Alliance has not shown through reasonable and supported assumptions that any of these sites need more capacity. Moreover, Alliance's premise that it will alleviate capacity constraints at UNC Chapel Hill fails to consider that UNC has a Policy AC-3 approved PET unit on its campus that is minimally utilized and another PET/MRI unit for which it projected and was approved to provide clinical PET scans at its BRIC location. Alliance has not presented any information regarding why UNC has not maximized the use of its existing three fixed PET units and needs a mobile provider to expand capacity. Alliance has also not acknowledged the application filed by UNC – Chapel Hill in June 2021 for an additional fixed scanner that was denied by the Agency in November 2021. See Project I.D. No. J-012089-21. It is clear that there is no need for additional capacity at UNC – Chapel Hill.

For these reasons plus any additional reasons the Agency may discern, it is clear that Alliance's project is a duplication of existing services and should be found non-conforming with Criterion (6).

**Criterion (7)**

Alliance proposes an unusually widespread service area that will require significant coordination to execute on a weekly basis. Yet Alliance proposes only 1.0 FTE for a truck driver to drive a 700-mile round trip travel route 6 days per week with more than one stop per day, including set-up time. 1.0 FTE is completely unreasonable for the proposed route with operations six days per week, which should be 1.2 FTE.

Alliance also does not project sufficient PET/CT technologists for efficient operations. From an operational perspective and to optimize workflow, a ratio of 1 technologist for every 4 patients is most efficient. So, for instance, if serving 12 patients in one day, 3 technologists would be needed. With only 2.1 PET technologists, there is not enough staff to cover the six day a week route efficiently. Of note, Alliance affiliate MIPNC projected 4.6 FTE technologists and a 1.0 FTE technology supervisor in 2018, further calling into question the sufficiency of Alliance's staffing projections in the 2021 application. Alliance's projections are 3.5 FTEs short for technologists based on its prior application as shown below.

| Position | Alliance | MIPNC - 2018 |
|---|---|---|
| PET/CT Technologist Senior | 1.0 | 1 |
| PET/CT Technologist | 1.1 | 4.6 |
| PET/CT Assistant | 1.0 | 0 |
| Other (Manager Radiology) | 0.2 | 0.2 |
| Other (Tractor/Cab Driver) | 1.0 | 0.75 |
| **Total All Staff** | **4.3** | **6.6** |
| *Source: Form H* | | |

Alliance provides no reason why its staffing is so radically different this time. Alliance's proposed salary levels in 2023 are also much lower than proposed in 2018 for similar and identical positions. Alliance does not explain why it would be reasonable to believe that salaries have declined in the three years since the MIPNC application was filed. Similarly, Alliance does not explain how it will be able to recruit staff for such low salary levels as shown below. Specifically, the below table presents the MIPNC 2018 application projected salaries assuming a project start of CY 2022 in the first column. The second column presents those same salary projections inflated 2.5 percent to CY 2023, which are significantly higher than the 2023 projections by Alliance in its 2021 application, as shown in the third column.

**Alliance and MIPNC's Salaries by Position**

| Position | 2018 CON (CY 2022 Projection) | 2018 CON Inflated to 2023 | Year 1 2023 |
|---|---|---|---|
| PET/CT Technologist Senior | $ 103,382 | $ 105,967 | $ 89,000 |
| PET/CT Technologist | $ 86,151 | $ 88,305 | $ 82,000 |
| PET/CT Assistant | $ - | $ - | $ 42,000 |
| Other (Manager Radiology) | $ 111,997 | $ 114,797 | $ 106,000 |
| Other (Tractor/Cab Driver) | $ 78,797 | $ 80,767 | $ 70,000 |

Based on the aforementioned issues, plus any additional reasons the Agency may discern, Alliance should be found non-conforming with Criterion (7).

**Criterion (13c)**

Alliance's projected payor mix is unreasonable and unsupported. In fact, it would have been much more reasonable to show no payor mix as a mobile vendor than to attempt to calculate such a fantastical basis for projected payor mix. Instead of using actual payor mix for the sites it already serves, Alliance manufactures a projected payor mix based on the outpatient visits by payor in each hospital's LRA. These outpatient visits contain a huge variety of services, many unrelated to cancer, the main diagnosis associated with PET imaging, and with significantly different payor mixes. Alliance makes the same mistake with regard to payor mix for the new host sites. Alliance certainly could have requested information from UNC on actual payor mix including charity care, Medicaid and underserved patients from its existing and proposed host sites, but it did not do so. Alliance does not demonstrate that it will be accessible to medically underserved patients and should be found non-conforming with Criterion (13c).

**Criterion (18a)**

Alliance has not demonstrated need for additional capacity at existing sites or a need for the new sites. Alliance has failed to document that there are any capacity constraints within the proposed UNC sites that support the proposed project. Alliance's proposed project is not cost-effective, does not improve quality, and does not improve access to the services proposed, and most certainly will not have a positive impact on competition in the mobile PET/CT market. Approving the dominant provider of mobile PET services in North Carolina for a third mobile PET/CT scanner will only allow Alliance to increase its dominance.

Based on these issues, plus any additional reasons the Agency may discern, Alliance's application should be found non-conforming with Criterion (18a).

**FAILURE TO MEET PERFORMANCE STANDARDS**

10A NCAC 14C .3700 sets the criteria and standards for a Positron Emission Tomography Scanner. As such, 10A NCAC 14C .3703(a)(1) states that:

> *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project."*

As described herein, Alliance's application consists of several unreasonable and unsupported utilization assumptions. While Alliance presented a projection for all of the sites served by affiliate Alliance I and II, it did not present a projection for all UNC affiliated sites with respect to utilization and capacity to support the need for its project. Moreover, Alliance did not even acknowledge that UNC – Chapel Hill filed for a fourth fixed PET unit in June 2021 and was denied by the Agency. In other words, Alliance only showed UNC projections in the context of existing and proposed sites, rather than the UNC system as a whole. Moreover, Alliance's projections do not consider the actual historical utilization of each existing host site served by the proposed unit

or Alliance I and Alliance II. Finally, in projecting volume for host sites, Alliance did not provide a reasonable basis for the starting first year scans with a consideration of how such projections may reflect shifts from other providers and may impact utilization across all three mobile units. Given these flaws, Alliance's projected utilization is unreasonable and unreasonable, and Alliance should be found non-conforming with the Performance Standards.

## COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, there is a need for one additional mobile PET scanner statewide; thus, although there are two applicants, only one can be approved in this review. NHFMC acknowledges that each review is different and, therefore, that the comparative review factors employed by the Project Analyst in any given review may be different depending upon the relevant factors at issue.

NHFMC has provided a detailed assessment of each application and its conformity with the CON Review Criteria and the Performance Standards for PET/CT set forth in 10A NCAC 14C .3703. It is clear that the Alliance application contain major flaws, particularly with respect to Criterion (3) – Need and Criterion (5) – Financial Feasibility that should result in denial of the application. Therefore, there should be no need for a comparative review. Nonetheless, NHFMC has provided the following comparative analysis. Some of the comparisons have been rendered inconclusive by the flaws in Alliance's utilization and financial projections. This analysis further confirms that not only is NHFMC the only approvable applicant based on the review criteria and performance standard but also that NHFMC is the comparatively superior application.

In order to determine the most effective alternative to meet the identified need for a mobile PET scanner in the state of North Carolina, NHFMC has reviewed and compared the following factors in each application:

- Conformity with Review Criteria
- Geographic Accessibility
- Effect on Competition
- Host Site/System Utilization and Need
- Proposed PET/CT Equipment
- Access by Underserved Groups
- Projected Average Operating Expense per PET Procedure
- Staffing
- Physician/Clinician Support

### Conformity with Review Criteria

As discussed above, only the NHFMC application is conforming to all applicable review criteria and rules. Therefore, the NHFMC application is the most effective alternative with respect to this factor.

**Geographic Accessibility**

Due to the unique nature of mobile services, there are several factors that must be considered when analyzing geographic accessibility, including total number of sites, number of proposed new sites, number of existing and approved providers in the service area, efficiency of providing services to the proposed service area, and need for expanded accessibility within the service area. The table below compares the number of new and existing proposed sites for each applicant.

| | NHFMC | Alliance |
|---|---|---|
| **Total # Sites** | 10 | 7 |
| **# New Sites** | 4 | 4 |
| **# of Counties** | 5 | 6 |

Each applicant proposes four new sites, which on the surface appears to be equal with respect to geographic access. NHFMC proposes to resume service to NH Thomasville Medical Center with the proposed unit, a site that it previously stopped serving due to capacity constraints. With this host site, NHFMC will technically add five sites.

As far as Alliance's new sites are concerned, a new site location only expands access if it is needed. Alliance has not justified need for a second mobile PET provider in Rockingham County where its existing mobile unit, Alliance I, already serves Annie Penn Hospital. In addition, UNC Chatham Hospital is a critical access hospital that cannot support a PET/CT service. Finally, UNC Chatham is only 35 miles from UNC - Chapel Hill, which has available PET/CT capacity.

Alliance proposes two new sites in Orange County (UNC Eastowne MOB and UNC Hospital – Hillsborough) purportedly to offload capacity constraints at UNC Hospital – Chapel Hill. (See CON application, page 57). Alliance has not documented that UNC's historical utilization warrants additional capacity, as it has three PET units that are not being fully utilized based on publicly available data. Please see Criterion (3) for additional discussion.

It is clear that Alliance's proposed project does not meaningfully expand geographic access to care. By contrast, NHFMC adds four new sites and resumes service to one site (NH Thomasville Medical Center) that is has been unable to serve recently due to capacity constraints. With regard to geographic accessibility, NFHMC is clearly the more effective applicant and should be approved.

It should also be noted by comparison that Alliance proposes to operate its unit just 5.75 days per week based on its projected utilization. By contrast, NHFMC has identified sufficient demand to operate both its new unit and existing units seven days per week.

**Effect on Competition**

In terms of competition, awarding an additional unit to Alliance will only serve to increase the competitive imbalance that already exists for mobile PET/CT services. Alliance currently operates two PET/CT units, NHFMC operates one, and Insight was recently approved to operate one unit.

If approved, Alliance will operate three units to NHFMC and Insight's one unit each, further diminishing competition for this service.

Based on this information, the NHFMC application should be found comparatively superior with respect to competition for the proposed mobile PET unit.

**Host Site/System Utilization and Need**

Both applicants are focused on serving the needs of a specific healthcare system. Alliance is focused on serving UNC and NHFMC is focused on serving Novant Health's Charlotte and Winston-Salem markets. Each applicant indicates that the mobile unit will address capacity constraints at existing host sites, add new host sites, and alleviate constraints at existing fixed PET sites within the target health system. The overarching question is which system has a greater need for additional capacity. In terms of fixed PET units within each system, the 2021 SMFP identifies that Novant Health's existing fixed PET units are operating at a higher percent of capacity than UNC.

| Facility | FFY 2019 Utilization | Units | Utilization Rate |
|---|---:|---:|---:|
| Novant Health Forsyth Medical Center* | 2,855 | 1 | 95.17% |
| Novant Health Presbyterian Medical Center | 2,151 | 1 | 71.70% |
| Subtotal Novant Health** | 5,006 | 2 | 83.43% |
| UNC Hospitals | 4,019 | 2 | 66.98% |

*Source: 2021 SMFP*
**The 2021 SMFP incorrectly identifies 2 fixed PET units at NHFMC. This has been brought to the Agency's attention and will be corrected in the 2022 SMFP.*
***Novant Health subtotal does not include Novant Health New Hanover Regional Medical Center in HSA V, which will not be served by the proposed mobile unit. NHRMC is operating at 83.73% capacity according to the 2021 SMFP.*

Based on this information, the NHFMC application should be found comparatively superior with respect to system need for the proposed mobile PET unit.

**Proposed Equipment**

As previously discussed, NHFMC proposes to acquire a PET/CT scanner that is identical to the current mobile scanner and the fixed PET/CT scanners at NH Forsyth Medical Center and NH Presbyterian Medical Center. This particular scanner was selected by the radiologists from Mecklenburg Radiology Associates and Triad Radiology Associates, the professional groups that support Novant Health's imaging services. By purchasing the same scanner, patients will be afforded the same high-quality standard of care, regardless of where the exam is completed. The table below presents the proposed PET/CT unit for each applicant.

**Summary of Proposed PET/CT Units**

| Applicant | NHFMC | Alliance |
|---|---|---|
| **PET/CT Unit** | Siemens Biograph mCT 40 | Siemens Biograph Horizon |

While Alliance's proposed PET/CT scanner meets basic quality standards, it appears that in an effort to save on cost, Alliance made the decision to switch vendors from the 2018 (GE Discovery IQ) to the 2021 (Siemens Biograph Horizon) application. The Siemens Biograph Horizon simply does not have the same capabilities as the previously proposed equipment in the 2018 application. Moreover, NHFMC's proposed PET/CT scanner (Siemens Biograph mCT 40) is comparatively superior to Alliance's proposed equipment in terms of capabilities. Specifically:

- NHFMC's proposed equipment utilizes technology that affords constant motion of the scanner bed with a speed that adjusts according to the body region being scanned, thus resulting in more efficient scanning;
- NHFMC's proposed scanner has a larger diameter bore that accommodates more comfortably bigger patients and reduce patient's claustrophobia; and
- NFHMC's proposed equipment has a longer tunnel length to accommodate an additional ring of detectors that affords a longer scan length thereby reducing the scan time needed (to cover the length of the patient's body).

Additionally, NHFMC's quote includes the Medrad Intego PET Infusion System. This infusion system is used to assure accurate delivery of the weight-based radiopharmaceuticals which in turn yields more reliable standard uptake values ("SUV") that are useful for assessing patient response to therapy. The Infusion System also reduces occupational radiation dose to the technologists who handle and work in close proximity to patients injected with radiopharmaceuticals.

With respect to quality of proposed PET/CT equipment, NHFMC is clearly the superior applicant and should be approved.

**Access by Underserved Groups**

*Payor Mix*

Comparison of access by underserved groups is difficult for any mobile service because the applicant is a vendor and not the direct provider of the service and therefore does not bill the patient or insurance carrier for the scans. For this reason, payor mix for mobile PET providers cannot be compared the same way that fixed PET and other imaging modalities can be compared. For this reason, it should not be assumed that any mobile vendor/applicant has the direct ability to fully control payor mix. However, this is particularly true for vendor-only entities like Alliance. By contrast, NHFMC is affiliated with the billing entity; as such, both entities have access to more information about the patient payor mix for the provider affiliate and the policies and procedures in place to ensure access to care.

In terms of projected payor mix, Alliance provides the payor mix for all existing outpatient services at their respective host sites as a basis for demonstrating access to underserved groups. These data

include a tremendous range of services well beyond imaging services that are not appropriate indicators of the payor mix for PET/CT services. This makes it impossible to make a fair comparison of payor mix for all applicants. Only NHFMC is both a vendor and a provider of mobile PET/CT services and can provide definitive payor mix data to demonstrate accessibility to care. Further, only NHFMC can provide and ensure that consistent financial access policies are provided across its proposed host sites.

**Comparison of Projected Payor Mix Information for Mobile PET/CT Service**

| Applicant | Projects for Mobile PET/CT Service Specifically | Source for Payor Mix Information |
|---|---|---|
| NHFMC | Yes | Actual Mobile Operations for Host Sites |
| Alliance | Yes | Provide hospital-wide, all outpatient payor mix for host sites. Not valid or meaningful for PET/CT |

*Source: Section L for each applicant.*

For these reasons, this comparative factor should be considered inconclusive.

*Charity Care*

Each applicant uses a different method of determining the amount charity care provided. Alliance projects its payor mix including charity care using overall outpatient payor mix for each host site. This methodology is flawed and unreasonable. By contrast, NHFMC has direct knowledge of the charity care provided by the host site and is able to demonstrate historical and projected write-offs for the actual charity care provided by each host site.

It should be noted that all host sites served by NHFMC provide services under the same charity care policies. This allows NHFMC to ensure that indigent populations have access to charity care. The following table shows the projection of charity care for each applicant and the source/method for presenting this information in each application.

**Comparison of Charity Care Projection by Mobile PET/CT Vendor**

| Applicant | Percent Charity Care | Source |
|---|---|---|
| NHFMC | 2.0% | Section L based on actual PET/CT payor mix for existing host sites |
| Alliance | 5.7% | Section L based on Outpatient Payor Mix for Host Sites |

This factor is inconclusive with respect to comparison between the applicants.

**Projected Average Charge to Host Site per PET Procedure**

Again, as mobile vendors, the applicants are not charging patients directly, and therefore, an analysis of patient gross and net revenue is not relevant. The vendor charge has no relationship to the ultimate charge to the patient/insurance carrier nor does the vendor charge have any impact on

the payment by the patient/insurance carrier. Moreover, Alliance's projected charge is questionable given that the charge is lower than presented in the application for affiliate MIPNC in 2018, and the charges are not inflated despite a 10 percent inflation factor identified in the sample host site agreement provided by Alliance. See Criterion (5) for discussion.

For these reasons, this factor should be considered inconclusive.

**Projected Average Operating Expense per PET Procedure**

NHFMC's expense per procedure is higher than Alliance; however, as discussed in detail in this submission, Alliance appears to have understated its salaries and FTEs. NHFMC projects more costs for direct expenses such as staffing to ensure that consistent, high quality services are provided on a timely and efficient basis. It is clear that NHFMC is devoted to ensuring that resources are directed toward expenses that impact the patient experience and quality of care.

**Comparison of Operating Expense per Scan**

| 3rd Full FY | NHFMC | Alliance |
|---|---|---|
| Total Expenses | $4,099,919 | $1,874,507 |
| Procedures | 4,351 | 2,921 |
| Operating Expense per Procedure | $942 | $642 |

As a direct comparison, this factor is inconclusive.

**Staffing**

The level of clinical staff presented by each applicant has a direct impact on quality of care. Alliance proposes only 1.0 FTE for a truck driver to drive a 700-mile round trip travel route six days per week with more than one stop per day, including set-up time. 1.0 FTE is completely unreasonable for the proposed route.

Alliance also does not project sufficient PET/CT technologists. Please see detailed discussion under Criterion (7). As shown below, Alliance has insufficient staffing and unreasonably low salaries compared to both NHFMC and the 2018 application filed by its affiliate MIPNC.

| | NHFMC* | Alliance | MIPNC - 2018 |
|---|---|---|---|
| Clinical FTEs | 4.8 | 3.1 | 4.6 |
| Non-Clinical FTEs | 1.35 | 1.2 | 0.95 |
| Total | 6.15 | 4.3 | 5.55 |
| Average Salary per Nuc Med Tech | $102,937 | $88,955 | $89,897 |

*Source: Form H, year 3*
**Staffing divided between 2 units*

To achieve the optimal outcome and ensure quality of care and patient safety, it is imperative that sufficient staffing is included. Given its understated staffing levels (see table above), it is not surprising that Alliance projects only 2.2 staff hours per scan, which is two-fold lower than NFMC's projected staff hour per scan of 4.59. For these reasons, NHFMC should be found the superior applicant.

| Project Year 3 | NHFMC | Alliance |
|---|---|---|
| Clinical FTEs | 9.6 | 3.1 |
| Projected Staff Hours | 19,968 | 6,448 |
| Total Scans | 4,351 | 2,921 |
| Staff Hours per Scan | 4.6 | 2.2 |

*Source: Form H and Form C.2b*

**Physician/Clinician Support**

While each applicant provides letters of support from physicians and other healthcare providers, the amount of physician/clinician support that can drive the success of the project varies among applications, as shown in the table below:

| Applicant | Physician/Clinician Letters of Support | Host Site Letters | Total Letters of Support |
|---|---|---|---|
| NHFMC | 39 | 10 | 49 |
| Alliance | 20 | 7 | 27 |

*Source: Alliance Application Exhibit C.4; NHFMC Application Exhibit C.1.1*

It should also be noted that the vast majority of physician letters provided by Alliance are from radiologists, who may read the PET images but do not refer or order such images. By contrast, NHFMC's physician letters are from oncologists, surgeons, chest specialists, radiation oncologists, and other physicians who actually generate the PET referrals.

Based on the letters of support provided in the applications that serve as referral sources, NHFMC is clearly the more effective alternative with regard to documentation of physician support.

**CONCLUSION**

Only NHFMC clearly meets all CON Review Criteria and the PET performance standards through reasonable and supported assumptions throughout its application. Further, NHFMC is dedicated to prioritizing superior quality PET/CT services. Even if Alliance met the CON Review Criteria and PET performance standards, which it does not, NHFMC is the superior applicant on a comparative basis to ensure access to care and provide the highest level of clinical quality to its proposed host sites and ultimately to patients. NHFMC should be approved.

## SUMMARY OF COMPARATIVE FACTORS

| Comparative Factor | NHFMC/Ranking | | Alliance/Ranking | |
|---|---|---|---|---|
| Expand Geographic Accessibility | Yes | 1 | Yes | 2 |
| Effect on Competition | Rank 1 | | Rank 2 | |
| Greatest System Need for the Project | Rank 1 | | Rank 2 | |
| Equipment Quality | Siemens Biograph mCT 40 | 1 | Siemens Biograph Horizon | 2 |
| Access by Underserved Groups: *Charity Care* | Inconclusive | | Inconclusive | |
| Projected Average Charge to Host Site per Procedure | Inconclusive | | Inconclusive | |
| Projected Average Operating Expense per PET Procedure(1) | Inconclusive | | Inconclusive | |
| Staffing: | | 1 | | 2 |
| *Total Clinical FTEs* | 9.6 | | 3.1 | |
| *Staff Hours per Scan* | 4.59 | | 2.20 | |
| Physician/Clinician Support | 39 | 1 | 20 | 2 |

*(1) Alliance does not provide sufficient staffing expense rendering a comparison of cost per scan inconclusive.*

# Attachment 1

# Court of Appeals Opinion

IN THE COURT OF APPEALS OF NORTH CAROLINA

2021-NCCOA-302

No. COA20-605

Filed 6 July 2021

Office of Administrative Hearings, No. 19 DHR 03066

MOBILE IMAGING PARTNERS OF NORTH CAROLINA, LLC, Petitioner,

v.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION, Respondent,

and

INSIGHT HEALTH CORP., Respondent-Intervenor.

Appeal by petitioner from final decision entered 20 February 2020 by Administrative Law Judge William T. Culpepper, III in the Office of Administrative Hearings. Heard in the Court of Appeals 9 June 2021.

*Wyrick Robbins Yates & Ponton LLP, by Lee M. Whitman and J. Blakely Kiefer, for petitioner-appellant.*

*Attorney General Joshua H. Stein, by Assistant Attorney General Derek L. Hunter, for respondent-appellee.*

*Fox Rothschild LLP, by Marcus C. Hewitt and Elizabeth Sims Hedrick, for respondent-intervenor.*

TYSON, Judge.

¶ 1 Mobile Imaging Partners of North Carolina ("Petitioner") appeals from a Final

Decision by an Administrative Law Judge ("ALJ") affirming the decision of the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section's ("DHHS") decision to approve InSight Health Corps' ("InSight") (together, "Respondents") application for a certificate of need ("CON") for a mobile PET/CT ("PET") scanner. This machine combines a positron emission tomography scan and a computerized tomography scan.

¶ 2 Petitioner appealed DHHS' decision to the Office of Administrative Hearings. In February 2020, the ALJ affirmed and entered a Final Decision for Respondents. Petitioner appeals. We affirm.

## I. Background

¶ 3 Petitioner is a joint venture between Alliance HealthCare Services Inc. ("Alliance") and University of North Carolina Rockingham Health Care, Inc. ("UNC-Rockingham"), a UNC-owned affiliate of the UNC Health Care System. Alliance operates two mobile PET scanners in North Carolina. InSight is a national provider of imaging services and offers mobile PET services in other states. Providers who desire to offer PET services within North Carolina must obtain a CON from DHHS. *See* N.C. Gen. Stat. §§ 131E-175 and -176(16)(f1)(8)(2019).

¶ 4 The 2018 State Medical Facilities Plan ("SMFP") identified a statewide need for one additional mobile PET scanner to operate within North Carolina. InSight, Petitioner, and two other organizations each submitted CON applications to be issued

the certificate for the additional mobile PET scanner pursuant to the SMFP.

¶ 5 Petitioner proposed to serve nine host sites across five of the six health service areas ("HSAs") established across North Carolina. InSight proposed to initially serve two host sites located in only one of the six HSAs. The last date to submit applications to DHHS was 1 December 2018. DHHS reviewed timely submitted applications.

¶ 6 Both Petitioner's and InSight's applications included a letter of support from the Caldwell Memorial Hospital ("Caldwell") signed by President/CEO Laura Easton. After applicants timely submitting their applications, Petitioner submitted written comments to DHHS within the form of another letter signed by Easton on 28 December 2018. This subsequent letter purportedly rescinded Caldwell's previous letter of support for InSight and advised DHHS that Caldwell was now fully supporting Petitioner's application. Without Easton's letter of support for Caldwell to host, InSight had only one remaining host site, Harris Regional Hospital, in Jackson County.

¶ 7 DHHS issued its decision approving InSight's application and disapproving the remaining applications in April 2019. DHHS found and concluded InSight, Petitioner and Novant each conformed with all applicable statutory review criteria and performance standards, but it awarded the CON to InSight based upon the comparative review.

## II. Jurisdiction

¶ 8 Petitioner's appeal is proper pursuant to N.C. Gen. Stat. §§ 131E-188(b) and 7A-29(a) (2019).

## III. Issues

¶ 9 Petitioner challenges whether InSight's application conformed with statutory criteria for the issuance of a CON. Petitioner argues InSight failed to meet Criterion 1 and did not satisfy the statewide need determination. Petitioner also argues the ALJ erred in concluding InSight's application conformed with Criterion 3 and 5 and concluding Petitioner's rights were not substantially prejudiced.

## IV. Standard of Review

¶ 10 This Court reviews a decision by the ALJ, and may reverse or modify the decision if:

> [T]he substantial rights of the petitioners may have been prejudiced because the findings, inferences, conclusions, or decisions are:
>
> (1) In violation of constitutional provisions;
>
> (2) In excess of the statutory authority or jurisdiction of the agency or administrative law judge;
>
> (3) Made upon unlawful procedure;
>
> (4) Affected by other error of law;
>
> (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or
>
> (6) Arbitrary, capricious, or an abuse of discretion.

N.C. Gen. Stat. § 150B-51(b) (2019).

¶ 11 Alleged errors in the ALJ's decision in categories one through four are reviewed by this Court *de novo*. N.C. Gen. Stat. §150B-51(c) (2019). Under *de novo* review, this Court "considers the matter anew and freely substitutes its own judgment for that of the lower tribunal." *Cumberland Cnty. Hosp. Sys., Inc. v. N.C. Dep't Health & Hum. Servs.*, 237 N.C. App. 113, 117, 764 S.E.2d 491, 494 (2014) (citations and internal quotations omitted). Categories five and six of N.C. Gen. Stat. § 150B-51(b) are reviewed under the "whole record" test. N.C. Gen. Stat. § 150B-51(c). Petitioner argues the issues before this Court are errors of law and subject to *de novo* review.

## V. Conforming with Criterion 1 and Statewide Need Determination

### A. Criterion 1

¶ 12 DHHS' review criteria are statutory and the first is referred to as "Criterion 1" throughout the record. Criterion 1 requires:

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

N.C. Gen. Stat. § 131E-183(a)(1) (2019).

¶ 13 "The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or

not in conflict with these criteria before a certificate of need for the proposed project shall be issued." N.C. Gen. Stat. § 131E-183(a).

¶ 14 The 2018 SMFP included a need determination for one additional mobile PET scanner statewide. We combine the analysis of Petitioner's first two issues in this section, because the answer to one will also necessarily answer the other.

¶ 15 Criterion 1 requires an applicant to demonstrate its application is "consistent with applicable policies and need determinations in the [SMFP]." N.C. Gen. Stat. §131E-183(a)(1). "Mobile PET Scanner" is defined as "a PET scanner and transporting equipment that is moved, at least weekly, *to provide services at two or more host facilities*." 10A N.C. Admin. Code 14C.3701.(5) (2019) (emphasis supplied).

¶ 16 All CON applications, including InSight's application, must demonstrate conformity with all statutory and regulatory review criteria. *See Presbyterian-Orthopaedic Hosp. v. N.C. Dep't Hum. Res.,* 122 N.C. App. 529, 534, 470 S.E.2d 831,834 (1996) (holding "an application must comply with *all* review criteria" and the failure to comply with one review criterion supports entry of summary judgment against the applicant) (emphasis in original).

¶ 17 "It is well settled that when a court reviews an agency's interpretation of a statute it administers, the court should defer to the agency's interpretation of the statute . . . as long as the agency's interpretation is reasonable and based on a permissible construction of the statute." *AH N.C. Owner LLC v. N.C. Dep't of Health*

*& Human Servs.*, 240 N.C. App. 92, 102, 771 S.E.2d 537, 543 (2015) (citation omitted). "It is proper to presume that an administrative agency has properly performed its official duties." *In re Broad & Gales Creek Cmty. Ass'n*, 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980).

¶ 18 "[The ALJ] is properly limited to consideration of evidence which was before the CON Section when making its initial decision." *Robinson v. N.C. Dep't of Health & Human Servs.*, 215 N.C. App. 372, 376, 715 S.E.2d 569, 571 (2011).

¶ 19 InSight pointed to Petitioner's effective monopoly on mobile PET services outside of Novant's services and facilities. InSight also described Petitioner's history of opposing opportunities to allow additional providers to introduce services to North Carolina's health care market. InSight predicted new providers would find it difficult to obtain public support for their applications, based upon feedback it had received from potential host sites, who were wary of taking action to put their current service with Petitioner at risk.

¶ 20 InSight proposed a statewide mobile PET route with the scanner moving weekly between six potential host sites in eastern, central, and western North Carolina. At least three potential host sites told InSight they would not provide documentation to support its CON application due to their concerns about Petitioner's reaction.

¶ 21 Petitioner undertook efforts to encourage InSight's two host sites to rescind

their support for InSight's CON application. Petitioner prepared draft rescission letters for both of InSight's host sites: Caldwell and Harris Regional. Caldwell's president signed the letter. Harris' did not.

¶ 22 Respondents set forth ample evidence before the DHHS and the ALJ showing any recission of support was the result of Petitioner's anti-competitive behavior to ensure it was awarded the CON.

¶ 23 Additional evidence led both DHHS and the ALJ to conclude that InSight's application met the two-host-site requirements notwithstanding Caldwell's recission letter. DHHS evaluated the recission letter, wrote two pages in its findings addressing the recission drafted by the Petitioner and explained why it did not affect InSight's conformity with Criterion 1. DHHS recognized Caldwell's recission letter did not indicate that Caldwell was no longer interested in a contract with InSight to the extent InSight was awarded the CON. The letter merely expressed a preference that Petitioner be awarded the CON. The ALJ was limited to the record evidence before the agency's hearing. *Robinson,* 215 N.C. App. at 375-76, 715 S.E.2d at 571 (citation omitted). Caldwell's president testified that if InSight had contacted her, she would have confirmed she would still consider contracting with InSight if it received the CON.

¶ 24 It cannot be said the ALJ's review and interpretation of DHHS' findings and conclusion that InSight met Criterion 1 is either unsupported or unreasonable.

Substantial evidence supports the conclusion that InSight's application complied with the host site requirement. Petitioner's argument is overruled.

### B. Statewide

¶ 25 Petitioner contends the term "statewide" in the SMFP means "throughout the State," while Respondents argue the term "statewide" means "anywhere in the State."

#### *1. Standard of Review*

¶ 26 Petitioner asserts the determination of whether an agency erred in its interpretation of a *statutory* term is entitled to *de novo* review. *Cashwell v. Dep't State Treasurer*, 196 N.C. App. 81, 89, 675 S.E.2d 73, 78 (2009); N.C. Gen. Stat. § 150B-51(b)(3). "When the issue on appeal is whether a state agency erred in interpreting a statutory term, an appellate court may freely substitute its judgment for that of the agency and employ *de novo* review." *Britthaven, Inc. v. N.C. Dept. of Human Resources*, 118 N.C. App. 379, 384, 455 S.E.2d 455, 460 (1995) (citation omitted). The SMFP created by DHHS uses the word "statewide" in the need determination, but the word "statewide" is not included in the statute, Respondent's administrative rules, or statutorily defined. N.C. Gen. Stat. § 150B-2(8a)(k) (2019).

#### *2. Interpretation*

¶ 27 Petitioner argues the ALJ failed to conduct any analysis of the evidence demonstrating Respondent's interpretation of "statewide" was contrary to: (1) the plain language of the need determination; (2) the rationale for the North Carolina

State Health Coordinating Council's inclusion of the need determination in the SMFP; (3) the CON statute; and (4) the policies in the CON Act.

¶ 28 The 2018 SMFP expressly concludes there is a "need for one additional mobile dedicated PET scanner statewide" and "the service areas listed in the table below need additional mobile dedicated PET scanners."

¶ 29 DHHS prepared the need determination pursuant to its discretionary authority granted by the General Assembly as part of the CON Act. *See* N.C. Gen. Stat. § 131E-177(4) (2019). Petitioner's argument, asserting the ALJ and DHHS misinterpreted its own meaning of "statewide," would require us to conclude DHHS abused its own discretion by determining InSight's application met DHHS' own meaning of "statewide." We conclude the ALJ properly upheld and concluded DHHS' interpretation of the term "statewide" was supported by substantial evidence. N.C. Gen. Stat. § 150B-51(b).

**C. Letter as Amendment**

¶ 30 DHHS asserts Caldwell's purported rescission letter was properly disregarded because it was an improper attempt by Petitioner to amend InSight's submitted application. "An applicant may not amend an application." 10A N.C. Admin. Code 14C.0204 (2019). Caldwell was not an applicant in this CON review. Rule .0204 does not apply as a matter of law because, here, a CON applicant was not seeking to amend its own application. *See In re Application of Wake Kidney Clinic,* 85 N.C. App. 639,

643, 355 S.E.2d 788, 790–91 (1987) ("The rules adopted by the Department of Human Resources to govern contested certificates of need hearings prevent a party from amending his application once it is deemed completed"). It stands to reason that if pursuant to Rule .0204 an applicant cannot "amend an application," then another applicant cannot amend a competitor's application. 10A N.C. Admin. Code 14C.0204; *see In re Application of Wake Kidney Clinic,* 85 N.C. at 643, 355 S.E.2d at 791. Petitioner's argument is without merit.

## VI. Criterion 3 and 5

### A. Criterion 3

¶ 31 Petitioner argues InSight's utilization and revenue projections were not reasonable nor adequately supported. "[F]indings of fact made by the agency are conclusive on appeal if they are supported by substantial evidence in the record reviewed as a whole." *Id.* at 644, 355 S.E.2d at 791. The ALJ reviewed DHHS' decision to determine if, based upon the information available to it, it was supported by evidence in the record and was reasonable. *Britthaven*, 118 N.C. App. at 382, 455 S.E. 2d at 459.

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

N.C. Gen. Stat. § 131E-183(a)(3).

¶ 32 The president of Strategic Healthcare Consultants, who was charged with "prepar[ing] certificate of need applications, provid[ing] healthcare consulting, and strategic planning services," testified the projections made in the application must be "reasonable and adequately supported" to conform with Criterion 3. To receive the CON in question, this Criterion required InSight to meet the performance standard, pursuant to 10A N.C. Admin. Code 14C.3703(a)(3), "of projecting of at least 2,080 PET" scans in the third operating "year following completion of the project."

¶ 33 "To fulfill its obligation of determining whether applications are consistent with statutory review criteria, [DHHS] must perform a meaningful analysis." *AH N.C. Owner*, 240 N.C. App. at 108, 771 S.E.2d at 547. DHHS performs a meaningful analysis by determining "whether an applicant conforms to [the criterion], [DHHS] must analyze and give due regard to the information available to it that is reasonably related to an applicant's history of providing quality care." *Id.* at 109, 771 S.E.2d at 547.

¶ 34 The ALJ made twenty-one findings of fact regarding Criterion 3 in the Final Decision. These findings of fact include:

> 56. . . . [P]hysicians are using PET for an increasing number of indications, [InSight] assumed that the demand for PET services will continue to increase in the future.

> . . . .
>
> 62. [InSight] projected that annual utilization of the proposed mobile PET scanner would exceed 2,080 procedures withing the first three years of operation based on assumptions described in its application.
>
> 63. [InSight's] projections relied on a "need-based" or "use rate" methodology to project demand based on application of the use rate to the population to be served. A need-based methodology is just one of many accepted metrologies used by healthcare planners. [DHHS] deemed [InSight's] used to a use rate/need-based methodology to be reasonable.
>
> 64. . . . [InSight] began by using data from the North Carolina Office of State Budget and Management to project the population in the counties to be served . . .
>
> 65. . . . [InSight's] calculation was based on historical use of both mobile and fixed PET scanners . . .
>
> . . . .
>
> 67. . . . [InSight] projected its anticipated market shares in the various counties that it proposed to serve. . . .

InSight incorporated these presumptions into its methodology to project the number of scans it would provide in the first three operating years, by applying the projected market share to the projected demand in each county. Petitioner's arguments were raised, responded to by InSight, and considered by DHHS. DHHS addressed these presumptions and found them to be reasonable and adequately supported.

¶ 35 DHHS and the ALJ's Final Decision addressed the bases for InSight's projections in detail and both determined that its demonstration of need and

projected utilization were reasonable and adequately supported. Substantial evidence supports the reasonableness and adequacy of InSight's projections. Petitioner's argument is overruled.

**B. Criterion 5**

¶ 36 Petitioner argues the ALJ's findings on Criterion 5 are unreasonable and not adequately supported.

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

N.C. Gen. Stat. § 131E-183(a)(5).

¶ 37 During the hearing, Martha Frisone, chief of the Health Care Planning and CON Section of DHHS, offered testimony. Her duties include directing and managing a team of twenty individuals in the implementation of North Carolina CON law. When asked about the requirements for Criterion 5, Frisone responded:

> There are several components. First, the financial and operational projections have to demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal based upon reasonable projections of the cost of and charges for providing health services by the person proposing the service.

¶ 38 When asked why InSight's application was found to conform with Criterion 5, Frisone replied, "they provided what the capital cost was. We were satisfied that it

was based on reasonable assumptions which were provided." The exchange between Frisone and counsel continued:

> [Frisone]: We were satisfied that they had adequately documented the availability of those funds, and we were satisfied that the projected utilization and projected cost and charges were reasonable and adequately supported.
>
> [Counsel]: Okay. And as you sit here today, do you have any reason to disagree with the [DHHS'] determination that InSight was conforming with Criterion (5)?
>
> [Frisone]: I do not.

¶ 39 Petitioner further argues Caldwell's President Easton, demonstrated InSight's projections were unreasonable. Petitioner relies upon Easton's testimony she "[did not] think" Caldwell needed twelve times its current service, she had "no reason to believe" that Caldwell could support 1,046 scans on a mobile PET per year, and Caldwell had not achieved a 95 percent market share in another service.

¶ 40 Easton did not share any concerns about InSight's projections with DHHS in the rescission letter or otherwise during testimony. Easton acknowledged Caldwell was losing volume to other health care providers because its access to mobile PET scanners is limited. She also conceded it was reasonable to expect Caldwell's volume to increase if it provided more services. Easton was unaware that InSight proposed to charge Caldwell a fee per scan and Caldwell would only have to pay the amounts InSight projected if it achieved the projected volumes to support it.

¶ 41 Evidence proffered at the ALJ hearing showed InSight anticipated helping

Caldwell increase its market share. Through increased access and resources, InSight would help Caldwell leverage existing and new referral relationships.

¶ 42 The ALJ stated DHHS' analysis relied upon four factors. "Of those four factors, Petitioner was found most effective on one factor and least effective on two factors. Novant was found most effective on one factor and least effective on one factor." Petitioner was found lacking in two areas, and InSight was found lacking only in one.

¶ 43 Substantial evidence supports the ALJ's conclusion DHHS acted reasonably and did not commit reversible error regarding review of InSight's projections. The ALJ's findings and conclusion that DHHS correctly determined InSight met the requirements of Criterion 5 is affirmed.

## VII. Petitioner's Substantial Rights

¶ 44 "[A] petitioner in a CON case must show (1) either that the agency (a) has deprived the petitioner of property, (b) ordered the petitioner to pay a fine or civil penalty, or (c) substantially prejudiced the petitioner's rights, *and* (2) that the agency erred." *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs.*, 235 N.C. App. 620, 624, 762 S.E.2d 468, 471 (2014) (emphasis in original).

¶ 45 Petitioner contends both DHHS and the ALJ erred by concluding Petitioner's rights were not substantially prejudiced. Without error in the underlying decisions, we need not reach this analysis. For the reasons described previously herein, we affirm the ALJ's Final Decision and decline to address Petitioner's argument on

prejudice.

## VIII. Conclusion

¶ 46 The ALJ reviewed DHHS' evidence and findings and heard arguments from DHHS and Petitioner. Substantial evidence supported DHHS' finding InSight complied with Criterion 1 and met the meaning of statewide in the ALJ's Final Decision to grant them the CON for the additional mobile PET scanner.

¶ 47 The ALJ also affirmed DHHS' finding InSight had complied with both Criterion 3 and 5 based upon DHHS' analysis of the evidence and requirements in InSight's application.

¶ 48 The ALJ Final Decision to affirm DHHS' CON designation as properly complying with the statutory CON requirements is affirmed. *It is so ordered.*

AFFIRMED.

Judges INMAN and ARROWOOD concur.