WRITTEN COMMENTS ON 2025 HEALTH SERVICE AREA I
FIXED PET SCANNER COMPETITIVE REVIEW

SUBMITTED BY NOVANT HEALTH LONG SHOALS IMAGING CENTER

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INTRODUCTION

The 2025 State Medical Facilities Plan (SMFP) identified a need for one fixed PET/CT scanner in Health Service Area I (HSA I). In response to the need determination, four applicants have submitted Certificate of Need (CON) applications, but only one applicant can be approved. The following providers submitted applications:

Project ID No.	Applicant	Referred to as
B-012684-25	Novant Health Inc. Novant Health Long Shoals Imaging, LLC	Novant Health or NH
B-012675-25	UNC Health Pardee	UNC Pardee or UNC
B-012688-25	AdventHealth Asheville	AdventHealth or AHA
B-012685-25	MH Mission Hospital, LLLP	Mission or MH

Pursuant to N.C. Gen. Stat. § 131E-185(a)(1), Novant Health Inc. and Novant Health Long Shoals Imaging, LLC ("NH"), submit the following comments pertaining to the applications filed by UNC Pardee, AdventHealth, and Mission to acquire a fixed PET/CT scanner in HSA I as identified in the 2025 SMFP. NH provides a comparative analysis of the applications followed by comments on individual applications. Other non-conformities may exist in the competing applications, and NH may develop additional opinions, as appropriate, upon further review and analysis. Nothing in these comments is intended to amend any statement in the NH application. To the extent the Agency deems any comment an amendment to the NH application, NH respectfully asks the Agency to disregard the comment.

In this competitive review, only one applicant can be approved. An approved applicant must demonstrate that it conforms to all applicable statutory and regulatory review criteria and is comparatively superior to the other applicants.

The only applicant that conforms to all statutory and regulatory review criteria is NH. The other three applications fail to provide reasonable and adequately supported utilization projections (Criterion (3)) and therefore are non-conforming with Criterion (5), the performance standard, and other criteria.

COMPARATIVE ANALYSIS OF THE COMPETING FIXED PET SCANNER APPLICATIONS

The following factors have been utilized in prior competitive CON reviews, regardless of the type of services or equipment proposed:

- Conformity with Statutory & Regulatory Review Criteria
- Competition (Access to a New or Alternate Provider)
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Historical Utilization
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Projected Average Net Revenue
- Projected Average Total Operating Cost

The following pages summarize the competing applications relative to the identified comparative factors.

Conformity to CON Review Criteria

Four CON applications have been submitted to develop a fixed PET scanner in HSA I. Based on the 2025 SMFP's need determination, only one fixed PET scanner can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by NH demonstrates conformity to all statutory and regulatory review criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming with All Applicable Statutory & Regulatory Review Criteria
Novant Health Inc. Novant Health Long Shoals Imaging, LLC	B-012684-25	**Yes**
UNC Health Pardee	B-012675-25	No
AdventHealth Asheville	B-012688-25	No
MH Mission Hospital, LLLP	B-012685-25	No

The NH application is based on reasonable and supported volume projections and reasonable projections of cost and revenues. As discussed separately in this document, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review criteria. Therefore, the **NH** application is the **most effective** alternative regarding conformity with applicable review Criteria.

Competition

Competition in the healthcare marketplace is a key factor in CON reviews. In this review, the three competing applicants currently offer, or are approved to offer, fixed PET services in HSA I. Mission has

one of the two existing fixed PET scanners in HSA I. UNC offers PET scans through a mobile PET service. AdventHealth has an approved but non-operating fixed PET scanner at its Hendersonville hospital. NH is the only applicant that would be a new provider of PET scans in HSA I.

Competition among providers is meant to elevate patient experience through reduced prices, improved service, and positive outcomes. Of the competing applicants, NH offers the lowest price (net revenue per scan). NH offers improved PET scan quality, leading to better outcomes, by choosing the Siemens Biograph Vision PET/CT (Siemens Vision) equipment, which is objectively superior to the GE Omni Legend PET/CT (GE Legend) the competing applicants chose. NH will accept referrals from all qualified physicians, regardless of their hospital affiliation. This will be true even if NH develops an acute care hospital in Buncombe County. Thus, the **NH** application is the **most effective** alternative with respect to competition.

Scope of Services

Regarding scope of services, the competing applications are each responsive to the 2025 SMFP need determination in HSA I for one fixed PET scanner. The table below compares the scope of services offered by each applicant. Generally, the application offering a greater scope of services is the more effective alternative for this comparative factor.

Scope of Services

Applicant	Proposed Scope of Services		
	Oncological PET	Neurologic PET	Cardiac PET
Novant Health	X	X	X
UNC Pardee	X	X	X
AdventHealth Asheville	X	X	X
MH Mission Hospital, LLLP	X	X	X

Source: CON applications.

The Siemens Vision scanner NH chose delivers higher-quality scans than the GE Legend chosen by the competing applicants. The Mission application says that several add-ons are needed for the GE to perform cardiac scans.[1] As the UNC and AHA applications do not specify these add-ons, it is unclear whether they can offer high-quality cardiac scans. Therefore, the **NH** application is a **more effective** alternative regarding scope of services.

Historical Utilization

In other competitive reviews, the Agency has compared historical utilization among the competing applicants and other PET providers in the HSA. There are three existing fixed PET providers in HSA I: Mission, Messino Cancer Centers (Messino), and Catawba Valley Medical Center (Catawba). Only two of the four applicants have existing fixed PET services in HSA I. AH Hendersonville has had an approved fixed PET scanner since 2023, but it was not operational as of the date of these comments. The table below

[1] Mission application, pp. 49–51.

summarizes FY 2024 utilization data for existing fixed PET scanners in HSA I and for mobile scans at UNC from the proposed 2026 SMFP.

Existing Provider or Applicant	PET Scanner Planning Inventory	FFY2024 Procedures	PET Utilization Rate*
Catawba	1	1,779	59.3%
Mission	1	1,893	63.1%
Messino	1	2,111	70.4%
AH Hendersonville	1^	0	0
UNC	Mobile	918	30.6%
Novant Health	0	0	0
AH Asheville	0	0	0

Source: Proposed 2026 SMFP, Table 15F-1: Utilization of Existing Dedicated Fixed PET Scanners.
*Based on a fixed PET scanner capacity of 3,000 procedures per unit.
^ AdventHealth Hendersonville was approved for a new fixed PET in 2023 that was not operational as of the date of these comments.

Of the four applicants:

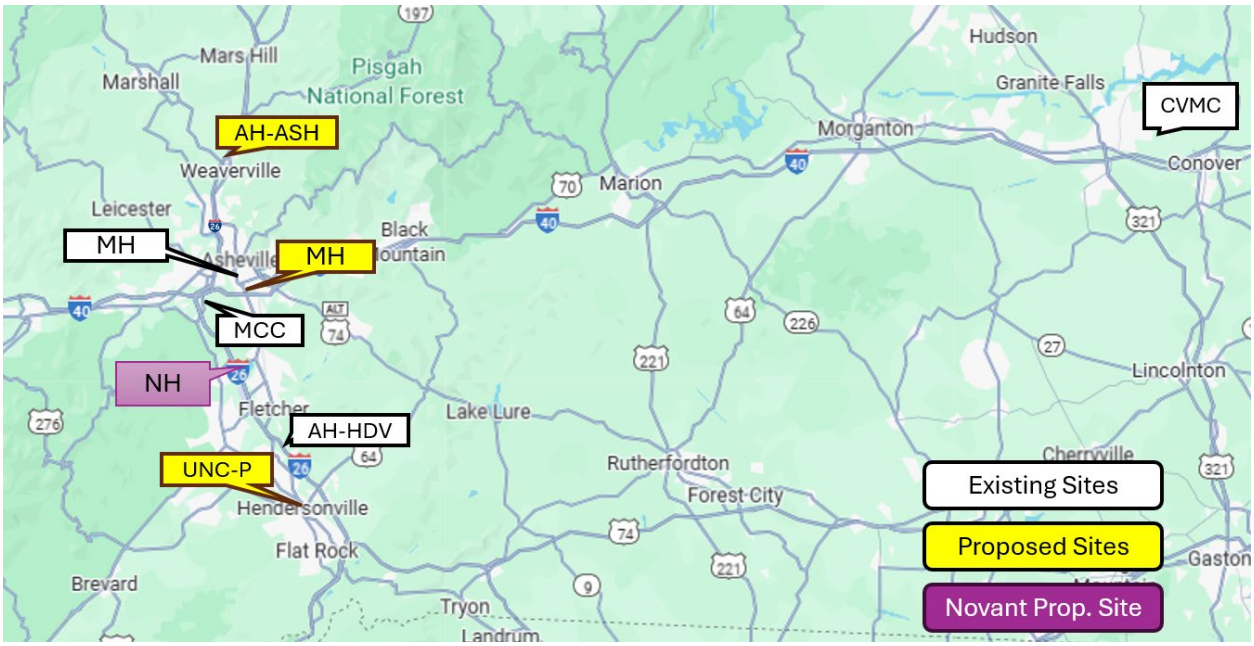
- Novant has no historical PET utilization in HSA I.
- AdventHealth has no historical PET utilization in HSA I. It has not implemented a PET CON it received in 2023 for AH Hendersonville.
- Mission had a major decline in PET utilization in FFY 2024, from 2,862 scans to 1,893 scans due to the opening of the Messino PET scanner. Mission's projections unreasonably assume the PET scanner at AH Hendersonville becoming operational in 2026 will not affect volume at Mission.[2] Mission performed 124 PET scans on Henderson County residents in CY 2024. If these 124 patients choose to receive their scans at AdventHealth in the future, Mission Hospital will not meet the performance standard in year three.
- UNC performed 918 PET scans in FY 2024 using a mobile scanner operated by Alliance. UNC states its volume was constrained because Alliance could not increase the time the mobile scanner was available to UNC. Overall utilization of that scanner in FY 2024 was 174%.[3]

Therefore, based on a comparison of historical PET utilization, **UNC** is the **most effective** alternative regarding this factor.

Geographic Accessibility

The map below shows the locations of the existing and approved fixed PET scanners in HSA I. The proposed locations for the new fixed PET scanner in HSA I are highlighted in yellow.

[2] Mission application, p. 145.
[3] Draft 2026 SMFP, p. 357.



In HSA I, existing and approved fixed PET scanners are located in Asheville, Hendersonville, and Hickory. UNC Pardee is also located in Hendersonville. Novant would be in Arden, and AdventHealth would be in Weaverville. All applicant locations are in Buncombe or Henderson Counties. The driving distance and time between Weaverville and Asheville is 10.2 miles, taking 14 minutes using Interstate Highway 26, according to Google Maps.[4] For a one-time diagnostic service for most patients, this is not a significant difference. The driving distance and time between Asheville and Hendersonville is 25 miles, equaling 32 minutes, also using I-26. Arden is about halfway between Asheville and Hendersonville.[5]

The service area for PET scans is all of HSA I. For a one-time diagnostic service for most patients, for residents of counties other than Buncombe and Henderson, the differences in overall travel times and distances to the nearest PET scanner are not great. The Agency should find comparison of the applicants inconclusive on this criterion.

Access by Service Area Residents

The 2025 SMFP defines the service area for a fixed PET scanner as "the HSA in which it is located (Table 15F-1)." Thus, the service area for this review is HSA I. The counties in HSA I are Alleghany, Ashe, Wilkes, Watauga, Alexander, Caldwell, Avery, Catawba, Burke, Mitchell, Yancey, McDowell, Rutherford, Cleveland, Polk, Henderson, Buncombe, Madison, Haywood, Transylvania, Jackson, Macon, Swain, Graham, Clay, and Cherokee.

The table below shows applicant patient origin projections for PET scans. None of the applicants project providing a substantial percentage of services to patients outside HSA I. There is no reason to think that

[4] AdventHealth says its Weaverville location is "located at the northern edge of Buncombe County just nine miles from Asheville. The site is easily accessible via I-26 and Highway 25/70 and is strategically positioned as a northern gateway to the region." AdventHealth application, p. 61.

[5] Weaverville, NC, to Asheville, NC, Google Maps, https://www.google.com/maps/dir/Weaverville,+North+Carolina/Asheville,+North+Carolina, as viewed on September 28, 2025.

providing services to patients from outside HSA I will limit access to services for HSA I residents. The Agency should find comparison of the applicants inconclusive on this criterion.

Applicant	Patient Origin – HSA I Counties	Patient Origin – Other Counties
Novant Health (Application p. 39)	97.6	2.4
UNC Pardee (Application p. 38)	93.9	6.1
AdventHealth Asheville (Application p. 72)	98.0	2.0
Mission (Application p. 60)	89.8	11.2

Access By Underserved Groups

Underserved groups are 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 are compared concerning two underserved groups: Medicare patients and Medicaid patients.[6] Access by each group is treated as a separate factor. The Agency may use one or more of the following metrics to compare the applications:

- Total Medicare or Medicaid procedures
- Medicare or Medicaid procedures as a percentage of total procedures
- Total Medicare or Medicaid dollars
- Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Medicare or Medicaid cases per procedure

The above metrics the Agency uses are determined by whether the applications included in the review provide data that can be compared as presented above and whether such a comparison would be of value in evaluating the alternative factors.

Here are the percentages for Medicare and Medicaid gross revenue from the financial schedules for the four applicants.

Projected Medicare Percentage Project Year 3, PET Services			
Applicant	**Medicare Gross Revenue**	**Total Gross Revenue**	**Medicare % of Total Gross Revenue**
Novant Health	$21,720,275	$30,721,747	70.7%
UNC Pardee	$23,263,226	$30,167,403	77.1%
AH Asheville	$39,163,032	$50,505,156	77.5%
Mission	$34,064,069	$48,070,676	70.9%

[6] Due to differences in definitions of charity care among applicants, comparisons of charity care are inconclusive.

Projected Medicaid Percentage Project Year 3, PET Services			
Applicant	**Medicaid Gross Revenue**	**Total Gross Revenue**	**Medicaid % of Total Gross Revenue**
Novant Health	$1,781,861	$30,721,747	5.8%
UNC Pardee	$1,441,905	$30,167,403	4.8%
AH Asheville	$3,038,924	$50,505,156	6.0%
Mission	$2,689,269	$48,070,676	5.6%

Any differences in the percentage of gross revenue for Medicare and Medicaid patients are likely due to statistical differences in how each applicant projected patient mix by payor and not to differences in access policies. The different methods can be summarized as follows:

- Novant's payor mix for the proposed PET/CT scanner is based on CY 2024 data for outpatient PET/CT scans on Mission Hospital's fixed PET/CT scanner. Mission's experience is a reasonable basis for projecting future payor mix, as it is a fixed PET/CT provider located in Buncombe County. This is the only fixed PET provider in Buncombe for which there is publicly accessible data, as Messino does not report into HIDI.
- UNC Pardee's payor mix for the proposed PET/CT scanner is based on the SFY 2024 actual payor mix for patients on the mobile scanner at its site, plus the estimated effect of Medicaid expansion. With the expansion of Medicaid coverage in North Carolina that began in December 2023, CY 2024 data indicate the anticipated payor mix shift has begun, with some patients previously classified as self-pay transitioning to Medicaid coverage. While many if not most of these patients may qualify for Medicaid; UNC Health Pardee conservatively projects 25% of remaining self-pay will shift to Medicaid.[7]
- AdventHealth Asheville's payor mix is based on AdventHealth Hendersonville's CY 2024 payor mix for mobile PET services.
- Mission's payor mix for the new PET scanner is assumed to be the same as the payor mix for the existing PET scanner. This payor mix was projected using the historic payor mix at Mission Cancer Center PET for the most recent completed fiscal year (1/1/2024–12/31/2024).

[7] UNC Pardee Application, p. 97.

Here are the percentages of Medicare and Medicaid patients in answer to Criterion 3, Question 6.b.

Estimated Percentage of Total PET Patients for Underserved Groups Criterion 3, Question 6.b.				
Group	**NH Asheville**	**Mission**	**AH Asheville****	**UNC Pardee**
Low-Income Persons	N/A	79.7%*	14.0%	N/A
Racial and Ethnic Minorities	4.9%	4.4%	11.0%	8.0%
Women	43.8%	43.5%	51.1%	60.8%
Persons with disabilities	N/A	N/A	*	N/A
Persons 65 and older	69.0%	69.3%	70.4%	61.1%
Medicare Beneficiaries	70.7%	65.5%	70.4%	61.9%
Medicaid Recipients	5.8%	5.2%	3.1%	9.6%

**Includes self-pay/charity and Medicaid patients.*

***Patient origin same as in the Hendersonville PET application (p. 66), per AH.*

The Agency should note the NH percentages of Medicare and Medicaid are consistent between the two metrics, while other applicants are inconsistent.

Depending on which metric is used, different applicants would be considered the most effective. In fact, there is no real difference among the applicants in access by Medicare and Medicaid patients. All applicants are enrolled as providers in both programs. There is no basis to think that any clinically qualified Medicare or Medicaid patients would be denied access to a PET scan. From a health planning perspective, there is no reasonable basis to prefer one applicant over another based on this criterion. The comparison on this criterion is inconclusive.

Projected Average Operating Expense/Scan

The table below presents the projected average operating expense per scan for the third year of operation for the applicants based on the information provided in Form C and Form F.3 of each application.

Average Operating Cost per PET Procedure Project Year 3			
Applicant	**Total # of Procedures**	**Total Operating Cost**	**Average Operating Cost/ PET Procedure**
Novant Health	2,481	$2,100,619	$846.68
UNC Pardee	2,696	$4,397,223	$1,631.02
AdventHealth Asheville	2,091	$3,810,974	$1,822.56
Mission	2,120	$4,889,300	$2,306.27

Source: Financial Pro Formas for each applicant.

NH has accurately accounted for all necessary operating expenses in its financial pro formas, allowing it to provide a wide range of PET imaging services for oncology, cardiology, and neurology patients. The three other applicants have much higher average operating costs. This is due to the difference in the choice of radiopharmaceuticals. Use of the recently approved and lower-cost radiopharmaceuticals

substantially lowers the average pharmaceutical cost per procedure and thus the average operating cost per procedure. The cost of recently approved radiopharmaceuticals is expected to decline as they become mainstream.

Average Pharmaceutical Cost per PET Procedure Project Year 3			
Applicant	**Total # of Procedures**	**Pharmaceutical Cost**	**Average Pharmaceutical Cost/ Procedure**
Novant Health	2,481	$462,368	$186.36
UNC Pardee	2,696	$2,866,601	$1,063.28
AdventHealth Asheville	2,091	$2,528,402	$1,209.18
Mission	2,120	$3,503,955	$1,652.81

Source: Financial Pro Formas for each applicant.

NH has the lowest operating cost per procedure. Therefore, the **NH** application is a **more effective** alternative regarding this comparative factor.

Projected Average Net Revenue/Scan

The projected average net revenue per scan is a comparative factor typically used by the Agency. The table below compares the average net revenue per scan for each applicant in Project Year 3. Because NH has lower pharmaceutical costs and lower operating costs per procedure, it can offer lower rates to commercial health plans and other payors. NH's average net revenue is about $1,000 to $1,500 less than the average net revenue for the competing applicants. Therefore, the **NH** application is a **more effective** alternative regarding this comparative factor.

Average Net Revenue per PET Procedure Project Year 3			
Applicant	**Total # of Procedures**	**Total Net Revenue**	**Average Net Revenue / PET Procedure**
Novant Buncombe	2,481	$4,081,511	$1,645.11
UNC Health Pardee	2,696	$7,095,040	$2,631.69
AdventHealth Asheville	2,091	$5,808,093	$2,777.66
MH Vanderbilt Park	2,120	$6,650,032	$3,136.81

Source: Financial Pro Formas for each applicant.

Summary

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed PET scanners that can be approved by the Healthcare Planning and Certificate of Need Section. The applicants collectively propose to develop four fixed PET scanners in HSA I. Based on the 2025 SMFP's need determination, only one fixed PET scanner can be approved.

The applications submitted by the competing applicants fail to conform to all applicable statutory and regulatory criteria. The comments below identify the relevant criteria for the individual applications.

The table below compares the applications on the comparative factors previously discussed.

Comparative Analysis of HSA I Competing Fixed PET Scanner Applications

Factor	Novant Health	UNC Pardee	AdventHealth	Mission
Conformity with Statutory & Regulatory Criteria	**Yes**	No	No	No
Competition (Access to a New or Alternate Provider)	**More**	Less	Less	Less
Scope of Services	**More**	Less	Less	Less
Historical Utilization	Less	**More**	Less	Less
Geographic Accessibility (Location in Service Area)	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense/Scan	**More**	Less	Less	Less
Projected Average Net Revenue/Scan	**More**	Less	Less	Less

NH's application is the more effective alternative for these factors:

- Conformity with Review Criteria
- Competition
- Scope of Services
- Geographic Accessibility
- Projected Operating Expense per Scan
- Projected Net Revenue per Scan

The only factor on which another applicant was more effective was Historical Utilization (UNC Pardee). Based on the previous analysis and discussion, the application submitted by **NH** is **comparatively superior** and should be approved in this competitive review.

NH is the only application fully conforming to all statutory and regulatory review criteria. Furthermore, NH is comparatively superior to all other applicants. Thus, the application submitted by **NH** is the **most effective** alternative and should be approved as submitted.

Individual Comments Regarding Applications

UNC Health Pardee

UNC Health Pardee (UNC) is non-conforming with these criteria:

- Criterion (3)
- Criterion (4)
- Criterion (5)
- Criterion (6)
- Criterion (8)
- Criterion (13)(d)
- Criterion (18a)
- 10A NCAC 14C.3703(a)(7)

Criterion (3) - G.S. 131E-183(a)(3): "The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed."

The UNC application is non-conforming with Criterion 3 in these regards:

- UNC's volume projections of oncology scans on pages 63 and 113 are not reasonable or adequately supported. UNC projects its utilization will grow at a CARG of 16.2% from FY 2025 to FY 2030. This is unreasonable because UNC ignores the fixed scanner at AH Hendersonville. In its discussion of need, UNC appears to assume the approved PET scanner at AH Hendersonville will be in service in 2026. UNC has no discussion of how Hendersonville or Henderson County needs or can fully utilize two fixed PET scanners, or if one fixed and one mobile PET scanner meets the needs of the population.
- UNC's projections of cardiology and neurology scans on pages 114–116 are unreasonable and not adequately supported. UNC ignores the fixed PET scanner at AH Hendersonville. UNC does not identify any physicians in the relevant specialties who have committed to refer patients to UNC for such scans instead of to other PET scanners.
- UNC discusses on pages 51 and 52 the "operational challenges of the mobile PET service." It ignores the fact that these challenges for patients will be removed when the AH Hendersonville fixed PET scanner becomes operational. If there are outages, delays, or bottlenecks with the mobile PET, these patients can be referred to AH Hendersonville.
- It seems likely that physicians practicing at AdventHealth were referring patients for PET scans. Unlike NH, UNC never identifies which referring physicians it expects to keep or calculates how many PET scans it will lose when the AH Hendersonville scanner is operational. Without accounting for this factor, it is unreasonable to project scans at UNC based on past growth rates.
- Within the five counties where UNC expects 94% of its patients to reside, only part of the clinically appropriate population will have access to the PET scanner.[8] The UNC application states only persons referred by "physicians who have admitting privileges at the hospital" will have access to PET services. PET scans are non-emergency, outpatient services.

[8] UNC Application, p. 99.

- A PET/CT scanner is intended to serve the population of all or most counties of HSA I. While there is a fixed PET scanner to the east at Catawba Valley Medical Center, there are no fixed PET scanners located to the west of Henderson and Buncombe Counties in the HSA. UNC projects about 94% of patients served will come from Henderson and adjacent counties (Transylvania, Buncombe, Polk, and Rutherford).[9] In "Other," it mentions Haywood, Macon, McDowell, Jackson, and Madison. It expects to serve no patients from Cherokee, Clay, Graham, or Swain to the west.

Criterion (4) - G.S. 131E-183(a)(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."

The UNC application is non-conforming with Criterion 4 in these regards:

- The discussion of the alternative to maintain the status quo of a mobile scanner at UNC does not consider how the new fixed scanner at AH Hendersonville will change the situation. The fixed scanner can better manage radiopharmaceuticals for cardiology and neurology scans while UNC focuses on oncology scans and refers patients needing cardiology or neurology scans.
- If UNC continues to use a mobile scanner in the near term, it can improve the pad and associated structures for the mobile PET. Almost all PET procedures are outpatient. There may be no reason for patients arriving for PET scans to enter the main hospital, since registration and pre-scan and post-scan waiting areas can be housed next to the pad for the mobile PET. Such improvements would be quicker and less expensive to implement than the fixed PET proposal.

Criterion (5) - G.S. 131E-183(a)(5): "Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

The UNC application is non-conforming with Criterion 5 in these regards:

- Because UNC's utilization projections for the fixed PET scanner are not reasonable or adequately supported, as discussed under Criterion 3, UNC has not shown the long-term financial feasibility of the proposal.
- UNC has not included the costs for a physicist as an employee or contractor on Form F.3b. UNC has not included expenses for medical supplies or other supplies on Form F.3b. There is no amount in "Other Expenses" that might cover the omitted expenses.
- UNC notes on page 85 that it does not currently employ PET technologists and will have to recruit, hire, and train them for the fixed PET scanner. However, UNC says it shows no start-up costs.

Criterion (6) - G.S. 131E-183(a)(6): "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

The UNC application is non-conforming with Criterion 6 in these regards:

[9] UNC Application, p. 38.

- This is an unnecessary duplication of an approved fixed PET scanner in Hendersonville. UNC has not shown that the combination of the AH Hendersonville fixed scanner and UNC's mobile scanner are not adequate to meet the needs of patients who would be referred to the two Hendersonville hospitals.
- The relatively small service area UNC defined for itself and the 68% of patients UNC expects from Henderson County reinforce the conclusion that one fixed and one mobile PET scanner in Hendersonville is sufficient.

Criterion (8) - G.S. 131E-183(a)(8): "The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system."

The UNC application is non-conforming with Criterion 8 in this regard:

- UNC has not demonstrated its proposed service will be coordinated with the existing health care system. It has not documented any communication or coordination with AH Hendersonville regarding plans to make its approved PET scanner operational.

Criterion (13)(d) - G.S. 131E-183(a)(13): "That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians."

The UNC application is non-conforming with Criterion (13)(d) in this regard:

- By allowing only "physicians who have admitting privileges at the hospital" (page 99) to refer patients for PET scans, UNC has unreasonably restricted access to its services for many people in Henderson County and in HSA I.
- UNC has made inconsistent statements about the percentage of its patients who will be covered by Medicare and Medicaid. On page 61, UNC says approximately 61% of its patients will have Medicare coverage and 9.6% will have Medicaid coverage. On page 98, UNC says 77.1% of its patients will have Medicare coverage and 4.9% will have Medicaid coverage. Page 98 says only 9% of patients receiving PET scans are covered by commercial insurance. UNC used the latter percentages in its pro forma.

Criterion (18a) - G.S. 131E-183(a)(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."

The UNC application is non-conforming with Criterion (18a) in these regards:

- Approval of UNC would not add a new PET provider to HSA I. UNC is already a PET provider.
- There is no evidence showing that there is currently an access problem for PET scans in Henderson County or HSA I. Mission is operating well below the performance standard, and Messino has unused capacity. If UNC patients are waiting two weeks or longer for a PET scan, it

is because UNC is hoarding patients instead of referring them to a PET scanner with available capacity.

- There is no reason to think UNC could have the "first operational fixed PET scanner in Henderson County." AH Hendersonville has represented to the Agency that its PET scanner will be operational in CY 2026. UNC, if approved, does not project it would offer services until March 2027. It could meet that date only if the Agency's initial decision is not appealed.

10A NCAC 14C.3703(a)(7): "Project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project."

The UNC application is non-conforming with the performance standard in this regard:

- As discussed under Criterion (3), UNC's utilization projections are not reasonable or adequately supported. They do not take account of the fixed PET scanner at AH Hendersonville becoming operational in 2026. There is no reasonable certainty UNC can perform 2,080 scans in its third full year of operation.

For the reasons stated above and any others the Agency may discern, the Agency should deny UNC's CON Application.

AdventHealth Asheville

Advent Health Asheville is non-conforming with these criteria:

- Criterion (3)
- Criterion (4)
- Criterion (5)
- Criterion (6)
- Criterion (18a)
- 10A NCAC 14C.3703(a)(7)

Criterion (3) - G.S. 131E-183(a)(3): "The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed."

The AHA application is non-conforming with Criterion (3) in these regards:

- The AdventHealth Asheville (AHA) application is formatted as a change of scope to Project ID B-12233-22 and B-12526-24 for a new acute care hospital in Weaverville. The proposed scope change involves the development of a fixed PET scanner. Mission has appealed the Agency approval of the prior projects, and there was no final decision by the date of these comments. AHA could have filed this application separately from the hospital application and not as a change of scope. Because this is a change of scope of the hospital applications, if those applications are finally denied, this application would also be denied regardless of the Agency action on the change of scope. This adds a layer of uncertainty to this application as to when and whether the population to be served would have access to the proposed services.

- The geographic access rationale for placing a fixed PET scanner in Weaverville is much weaker than the rationale for locating an acute care hospital there. The driving distance and time between Weaverville and Asheville is 10.2 miles and 14 minutes using I-26, according to Google Maps. AHA says the distance is only 9 miles.[10] For a one-time diagnostic service for most patients, this is not a significant difference. Any shorter drive for residents of Avery, Madison, Mitchell, and Yancey Counties is offset by the longer drive through Asheville for the more numerous residents of counties to the west of Buncombe County. The Weaverville location is less accessible than an Arden location for most residents of HSA I.
- The AHA utilization projections are not reasonable or adequately supported. The assumed market shares on page 131 are arbitrary and unsupported by any analysis. The patient origin tables on pages 72 and 133 show patients coming to Weaverville from Henderson (390), Polk (35), Transylvania (40), and Rutherford (117) Counties. Assuming the AH Hendersonville fixed PET scanner will be operational in 2026 as AdventHealth told the Agency, this makes no sense. AHA offers no reason patients from these counties would bypass fixed PET scanners at AH Hendersonville, Mission, and Messino to reach Weaverville. AHA projects 2,091 total scans for the third full year, only 11 scans above the required minimum. Removing only the projected 390 scans from Henderson County means AHA would not meet the performance standard.
- In the unlikely event AHA did draw the projected patients to Weaverville, AHA would cannibalize the utilization at AH Hendersonville. The applicant arbitrarily asserts on page 134 that AH Hendersonville would still meet the performance standard in its Year 3. However, it offers no analysis to support these numbers.
- AdventHealth has not shown it can develop fixed PET services in a reliable and timely manner. It has offered no details on how the hurricane has prevented it from implementing its 2023 CON, Project ID B-12331-23. In a similar period, Messino HSA implemented its fixed PET. The Agency should not award AdventHealth another CON for a fixed PET scanner until it implements the 2023 CON.

Criterion (4) - G.S. 131E-183(a)(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."

The AHA application is non-conforming with Criterion (4) in these regards:

- AHA has not presented valid reasons why use of a mobile PET scanner is not a more effective alternative than a fixed PET scanner for initial years of its Weaverville hospital.
    - AHA proposes locating the fixed PET scanner in a building separate from the hospital. Therefore, a mobile or fixed PET will be physically separated from the hospital environment. Because PET scans are a non-emergency outpatient procedure, there is usually no reason for a patient to enter the hospital unless the scanner is inside the hospital.
    - AHA did not document any communication with mobile PET vendors to determine the availability or cost of mobile PET services in Weaverville. The initiation of fixed PET services in Henderson County will likely reduce demand for mobile PET services in Hendersonville and increase availability for mobile PET services at Weaverville.

[10] AdventHealth application, p. 61.

    - The mobile PET services include the equipment and staff to operate the scanner. AHA documented no analysis comparing the capital and operating costs of fixed and mobile PET scanners for the first three years of operation.
- As discussed above, AHA has not shown it can meet the performance standard for a fixed PET scanner at Weaverville. A mobile PET scanner may be the only feasible alternative for PET services at Weaverville.
- Maintaining the status quo would mean patients who might have used a fixed PET scanner at Weaverville would likely continue to use PET scanners in Asheville, 9 miles away per AHA. With the addition of the Messino PET scanner, there is capacity for 6,000 scans per year in Asheville. The two Asheville scanners are now providing most of the scans that would be done in Weaverville. The opening of the fixed scanner at AH Hendersonville in 2026 will shift patients from the Asheville scanners, making more capacity available to residents of the northern counties.

Criterion (5) - G.S. 131E-183(a)(5): "Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

The AHA application is non-conforming with Criterion (5) in these regards:

- Because AHA's utilization projections for the fixed PET scanner are not reasonable or adequately supported, as discussed under Criterion 3, AHA has not shown the long-term financial feasibility of the proposal.
- AHA defines overhead expense (p. 142) as "overhead based on a percentage of net revenue and … applied to projected net revenue. Overhead expense includes but is not limited to accounting, billing, human resources, information technology, scheduling, and all other costs necessary to provide patient services based on the applicants' experience." Therefore, there should be an overhead amount on F.3b, but there is not.
- AHA will have to recruit, hire, and train additional technologists for the Weaverville fixed PET scanner. UNC shows no start-up costs, however (p. 84).

Criterion (6) - G.S. 131E-183(a)(6): "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

The AHA application is non-conforming with Criterion (6) in this regard:

- The proposed Weaverville fixed PET scanner is an unnecessary duplication of the capabilities of the AH Hendersonville fixed PET scanner based on the patient origin on pages 72 and 133 of the AHA application. The AH Hendersonville scanner is projected to perform 2,124 scans in 2029. This scanner therefore has the capacity to scan the 582 patients projected for Weaverville in Year 3 from Henderson (390), Polk (35), Transylvania (40), and Rutherford (117) Counties.

Criterion (18a) - G.S. 131E-183(a)(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."

The AHA application is non-conforming with Criterion (18a) in these regards:

- Because of the approved fixed PET scanner at AH Hendersonville, AHA will not be a new fixed PET provider in HSA I.
- The counties from which AHA's patients are projected to come completely overlap the counties from which AH Hendersonville's patients are expected to come. Therefore, AHA is not needed for AdventHealth to provide competition for fixed PET services in HSA I.
- There is no evidence showing that there is currently an access problem for PET scans in Buncombe County or HSA I. Mission is operating well below the performance standard, and Messino has unused capacity. AH Hendersonville is not yet in operation.

10A NCAC 14C.3703(a)(7): "Project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project."

The AHA application is non-conforming with the performance standard in this regard:

- As discussed under Criterion (3), AHA's utilization projections are not reasonable or adequately supported. They assume 390 patients from Henderson County in Year 3, despite AH Hendersonville becoming operational in 2026. There is no reasonable certainty AHA can perform 2,080 scans in its third full year of operation.

For the reasons stated above and any others the Agency may discern, the Agency should deny AdventHealth's CON Application.

Mission Hospital Vanderbilt Park (Mission)

Mission is non-conforming with these criteria:

- Criterion (3)
- Criterion (4)
- Criterion (5)
- Criterion (6)
- Criterion (18a)
- 10A NCAC 14C.3703(a)(7)

Criterion (3) - G.S. 131E-183(a)(3): "The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed."

The Mission application is non-conforming with Criterion (3) in these regards:

- The "existing capacity limitations" Mission references on page 34 ceased to exist when the Messino fixed PET scanner became operational in 2024 and Mission's volume dropped sharply to 1,723 in 2024, below the performance standard. It will likely drop further when the AH

Hendersonville fixed PET scanner becomes operational in 2026. Mission has plenty of unused capacity for cardiac scans.

- On page 53, Mission says it operates a Siemens Biograph mCT PET/CT scanner focused primarily on oncology PET scans and neuroendocrine PET studies at this location. Mission does not say it cannot perform acceptable cardiac scans with this equipment, or that it could not upgrade the Siemens equipment for cardiac scans. If the Siemens PET scanner is not optimal for cardiac scans, Mission can replace it with the equipment described on pages 49–53 without a CON.
- Most PET scans are non-emergency outpatient procedures. If Mission thinks it is better for patients to locate a PET scanner in a medical office building, it can relocate its existing scanner or replace it with a new scanner at the Vanderbilt Park location without a CON.
- The Mission CAGR from 2020 to 2024 or estimated 2025 is negative (p. 145). There is no reasonable basis to use a single year (2024–2025) to project volume six years in the future (p. 146). This projection does not consider the impact of AH Hendersonville.
- Mission's projection of the cardiac scans it would perform are not reasonable or adequately supported.
    - Mission says the cardiac scan projections are based on a study by The Advisory Board (TAB) (p. 147). However, Mission did not provide a full citation for the study and did not make a copy available to the Agency or the public to verify the sources or methods behind the numbers. An undisclosed TAB document cannot be a reasonable basis for utilization projections.
    - Mission has no reasonable basis to assume it would capture 70% to 85% of cardiac scans for HSA 1. A PET scan is a non-emergency outpatient diagnostic procedure. There is no necessary relationship between the facility doing the scan and the facility where any treatment occasioned by the scan is performed. This projection does not consider the impact of the fixed PET scanner at AH Hendersonville.
    - Existing PET/CT scanners are capable of performing cardiac scans. Mission is assuming an immediate explosion in the number of cardiac scans, with no reasonable basis. Without this explosion, and an unreasonably high market share, Mission cannot justify its utilization projections or meet the performance standard for two units.
- Even with its arbitrary, unsupported assumptions, Mission projects only 4,233 scans in the third year of the project. Since the projection completely ignores the impact of AH Hendersonville on Mission's volume, it is reasonably certain Mission will do fewer scans than it projects. If it does even 75 scans fewer than it projects (4,233 – 4,160 =73), or a difference of 1.8% of its projected volume, it will not meet the performance standard for two units.

Criterion (4) - G.S. 131E-183(a)(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."

The Mission application is non-conforming with Criterion (4) in these regards:

- The main theme of this application is Mission needs a second unit equipped to perform cardiac scans and the additional capacity to do cardiac scans without crowding out its current oncological and neurological scans.
- Mission failed to identify the alternative of having one PET scanner and upgrading or replacing that scanner as it thinks best for all types of scans. The one scanner can be placed at its current

location, the Cancer Center, or at Vanderbilt Park as Mission thinks best. This alternative is less costly and more effective for these reasons:

- It recognizes that Mission's total PET scan volume has declined will not increase at past rates because of the presence in HSA I of Messino and AH Hendersonville fixed PET scanners and continued operation of mobile scanners.
- The alternative does not require competitive CON approval, so Mission can proceed more rapidly (particularly if there is an administrative hearing).
- The operating costs of one fully utilized PET scanner are much less than the operating costs of two less utilized PET scanners.
- Other existing and approved fixed PET scanners will be better utilized.

Criterion (5) - G.S. 131E-183(a)(5): "Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."

The Mission application is non-conforming with Criterion (5) in these regards:

- Because Mission's utilization projections for the fixed PET scanners are not reasonable or adequately supported, as discussed under Criterion 3, Mission has not shown the long-term financial feasibility of the proposal.
- Statements about staffing in the application are inconsistent. Pages 164 and 166 say there will be only one tech required for the new PET/CT scanner and one RN for cardiac testing. Page 168 says there will be two techs for each scanner, but the dollars shown are for only one tech. Mission does not explain why the scanners are staffed differently.
- Fully staffing a tech position requires 1.25 FTEs even for outpatient services to cover planned and unplanned leave. The staffing budget for the application is insufficient.
- Mission has no operating expense budget for medical supplies, other supplies, overhead, or depreciation of building improvements. There is no rental expense for the space. The $54,000 budgeted for "Other Expenses" is insufficient to cover these omissions.

Criterion (6) - G.S. 131E-183(a)(6): "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."

The Mission application is non-conforming with Criterion (6) in this regard:

- The Mission application is an unnecessary duplication of the PET/CT capacity needed at Mission. It does not need a second scanner for the reasonably expected scan volume in the planning period.

Criterion (18a) - G.S. 131E-183(a)(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."

The Mission application is non-conforming with Criterion (6) in this regard:

- Approval of the Mission application will have an adverse impact on competition for PET/CT services in HSA I by preventing the Agency from approving an application for a new fixed PET/CT provider in HSA I.
- At its reduced volume, Mission has the unused capacity to compete for more scans with one scanner. It can compete through improvements in its equipment for improved scan quality, increasing its ability to offer cardiac scans, and giving commercial insurance plans more favorable rates.

10A NCAC 14C.3703(a)(7): "Project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project."

The Mission application is non-conforming with the performance standard in this regard:

- As discussed under Criterion (3), Mission's utilization projections are not reasonable or adequately supported. They do not address the likely impact of AH Hendersonville on Mission's volume. They make arbitrary and unsupported assumptions about the needed number of cardiac scans, and the percentage of those scans Mission would perform. There is no reasonable certainty Mission can perform 4,160 scans with two units in its third full year of operation.

For the reasons stated above and any others the Agency may discern, the Agency should deny Mission's CON Application.