

**Petition for Adjusted Need Determination for  
One Additional Dedicated Fixed PET Scanner in HSA V**

**PETITIONER**

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**STATEMENT OF REQUESTED ADJUSTMENT**

Southeastern Health (SeH) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination in the *2020 State Medical Facilities Plan (2020 SMFP)* for one additional dedicated fixed PET scanner in Health Service Area (HSA) V designated for Robeson County.

**EXECUTIVE SUMMARY**

SeH currently provides PET services through a vendor-owned mobile scanner. Given its high volume of cancer patients, its status as the only provider of open heart surgery without a fixed PET scanner in the county, and the unique demographic characteristics of the Robeson County population, SeH needs access to a full-time fixed PET scanner.

**Key Findings:**

In summary, Robeson County has a need for a fixed PET scanner based on the following unique characteristics:

- SeH is the only provider of open heart surgery without access to a fixed PET scanner in its home county.
- If approved for its second linear accelerator in September 2019, as expected, SeH will be one of only two hospitals in the state with two or more linear accelerators but no fixed PET scanner in the county.
- Three counties with a smaller population than Robeson County have fixed PET scanners.
- Without approval of the petition, it would be at least five years or more before the standard methodology generates a need for a fixed PET scanner based on SeH's linear accelerator volume.
- Given the extreme health disparities in Robeson County, the development of a fixed PET scanner in the county is needed to improve access to PET imaging for oncology, cardiac and other conditions.

## **BACKGROUND**

SeH is a non-profit health system that has served the residents of Robeson County and surrounding communities for more than 65 years. SeH is currently licensed for 452 beds, including acute care, psychiatric, inpatient hospice, and long-term care beds. The system employs more than 2,200 people and has 115 active medical staff. Over the past two years, the community SeH serves has endured two major weather events in Hurricanes Matthew and Florence, both of which flooded and cut off power to homes and, for a time, SeH as well. Despite these devastating events, SeH continues to care for all patients, regardless of their ability to pay. SeH provides advanced services in cardiology, cardiac surgery, pulmonology, and oncology, among others, making tertiary services available to a multi-county region.

SeH's oncology services are housed in the Gibson Cancer Center, which offers radiation oncology, medical oncology, and blood disorder treatments. Also available are the comprehensive support services of an on-site pharmacy and laboratory, information resource library, oncology therapist and dietitian. In cooperation with the local chapter of the American Cancer Society, the Gibson Cancer Center offers support groups and educational programs. Affiliations with Duke Medicine for medical oncology services and Southeastern Radiation Oncology for radiation oncology services bring world class clinical care to Gibson Cancer Center; accreditation by the American College of Surgeons Commission on Cancer ensures that care is on par with the best community cancer programs in the country. The Gibson Cancer Center currently has one linear accelerator and has filed a Certificate of Need (CON) application for a second linear accelerator. A decision on that CON application, which was not competitive, is expected before the end of September 2019.

Since 2006, Southeastern Health Heart and Vascular Center has provided comprehensive cardiac care, including cardiac valve surgery, Percutaneous Cardiovascular Intervention (PCI), and an open heart surgery program, the most recent to be developed in North Carolina. SeH provides these services in partnership with Duke Health, which ensures patients have local access to a high quality program. Since its development, more than 600 patients have received cardiac surgery provided by Duke Health surgeons at Southeastern Health.

SeH currently provides PET services through a vendor-provided mobile service, which is on site one half-day (Monday) per week. While the mobile service has provided some local access to PET services, it does not and cannot meet the need for PET services in Robeson County and the surrounding area. As a result, patients needing a PET scan must either travel a significant distance to another site, must delay diagnosis, staging and treatment for their cancer until the mobile PET is on site with available appointments, or forgo a PET scan and rely on another, less-effective diagnostic procedure.

## **REASON FOR THE REQUESTED ADJUSTMENT**

The current methodology for fixed dedicated PET scanners has evolved over the past two decades, as the technology has become more central in diagnosing, staging and re-staging cancer, as well as for cardiac and neurological studies. In order to most effectively understand why the current methodology does not

address the particular need at SeH, it is important to know the history of the PET methodology in North Carolina over the past two decades.

In 2000, the only PET scanners in the state were located at four of the five academic medical centers. After increasing evidence of the efficacy of PET scanners for diagnosing disease and as an adjunct to treatment of cancer and other conditions, the Centers for Medicare and Medicaid Services began expanding the clinical conditions for which it reimbursed for PET. In response to the increased understanding of the use of clinical PET and the expanded reimbursement for the service, the SHCC began to slowly and deliberately increase the number of PET scanners in the state. A methodology for fixed dedicated PET scanners first appeared in the *2001 SMFP*, which resulted in the allocation of one additional PET scanner in each of the six HSAs. In order to be approved, the applicant had to be all of the following:

- A hospital;
- A provider of open heart surgery;
- A comprehensive oncology provider (medical, surgical and radiation);
- A provider with a multi-county service area; and,
- A teaching site for post-graduate medical education.

These conditions ensured that the expansion of PET services across the state would first occur at sites where they could be most effectively used, at teaching hospitals providing comprehensive oncology and cardiac services.

The *2002 SMFP* had no need for additional fixed PET scanners but allocated two mobile PET scanners to serve the state.

As the SHCC continued to address the need for more PET scanners across the state, the PET methodology in the *2003 SMFP* was broadened to include two-parts, one for existing PET providers and a second for major cancer centers. This methodology was essentially the same as the current methodology, although the capacity assumptions for PET scanners and other minor changes have been made since that time. As with previous years, a key provision of the methodology was a definition of “qualified applicant,” which included the following, but could be met by one member of a joint venture for the service:

- Location within the HSA in which it applied;
- Provider of open heart surgery;
- Provider of comprehensive oncology services; and,
- Service to patients from a multi-county region.

By 2006, each hospital in North Carolina that met these requirements had had the opportunity to apply for a PET scanner. Specifically, by that year, every hospital in North Carolina that provided open heart

surgery had obtained a CON for a fixed PET scanner,<sup>1</sup> including the three providers in HSA V that currently have fixed PET scanners. In order to continue expanding PET services, the *2006 SMFP* removed the requirement that applicants provide open heart surgery. That same year (2006), SeH performed its first open heart surgery in Lumberton. Since that time, SeH has continuously met all of the original requirements to be a “qualified applicant,” providing open heart surgery and comprehensive oncology services to patients from a broad region, and serving as a teaching site for both medical students and post-graduate residents.

The *2009 SMFP* shows the results of the SHCC’s deliberate efforts in expanding PET services across the state: 27 providers of fixed PET services, with 22 additional sites hosting mobile scanners. While this expansion provided access to PET services broadly across the state, the number of PET scanners in service, combined with the economic downturn of the late 2000s and increasing requirements by payors requiring prior authorization for PET scans resulted in the following limited PET determinations in the years to follow:

- 2009 SMFP: no need
- 2010 SMFP: no need
- 2011 SMFP: no need
- 2012 SMFP: no need
- 2013 SMFP: one PET scanner in HSA II
- 2014 SMFP: no need
- 2015 SMFP: no need
- 2016 SMFP: no need
- 2017 SMFP: one PET scanner in HSA IV
- 2018 SMFP: one mobile PET scanner
- 2019 SMFP: one PET scanner in HSA IV

The last fixed PET scanner awarded in HSA V was in the *2003 SMFP*. While mobile sites have been added in the region, no additional fixed PET scanners have been approved in HSA V in the past 16 years. As a result of the timing of the commencement of open heart surgery at SeH, combined with the overall development of PET scanners across the state, SeH is the only open heart surgery provider in the state without a fixed PET scanner in the county. Further, assuming SeH is ultimately approved for its second linear accelerator, it will be one of only two hospitals in the state with two linear accelerators and no fixed PET scanner<sup>2</sup>.

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<sup>1</sup> Note that Carolinas Medical Center-Mercy was an open heart provider at that time; however, the health system (then known as Carolinas HealthCare System) applied for a second PET scanner at Carolinas Medical Center, located less than two miles away. Similarly, Duke Regional Hospital (then known as Durham Regional Hospital) did not apply for a PET scanner, but Duke University Hospital, located five miles away, applied for a second PET scanner. WakeMed developed a PET scanner as part of a joint venture with Wake Radiology.

<sup>2</sup> The only other hospital in this category is Carolinas HealthCare System Blue Ridge, which performs more than one-third less volume on its two linear accelerators than SeH does on its single linear accelerator.

While SeH does not believe the current methodology needs to be changed, given its provisions, it is unlikely that a need will be generated through which SeH can be approved for many years, based on the following:

- Part 1 of the Fixed PET Scanner Methodology is triggered when any existing provider reaches 80 percent of utilization. While one of the three providers in HSA V is approaching this level of utilization, the other two are at less than 40 percent of target utilization and unlikely to generate a need for many years. Even if the one provider does generate a need in the next few years, it is likely that it could more easily demonstrate need for a second PET scanner in a competitive CON review, given its historical utilization and the size of its service area.
- Part 2 of the Fixed PET Scanner Methodology is triggered by any “major cancer treatment facility” without a fixed PET scanner. This part of the methodology requires a provider to have two linear accelerators which have achieved 12,500 ESTVs. While SeH operates one of the most highly utilized linear accelerators in the state, and though it reasonably expects to be approved to develop a second linear accelerator in the next few weeks, it will be years before it can be developed and increase its volume to meet this requirement<sup>3</sup>. Further, the Chair of the SHCC has indicated that the linear accelerator methodology may need to be refined in the near future, particularly as the use of ESTVs to calculate capacity is somewhat outdated. Thus, the impact of these potential changes on the definition of “major cancer treatment facility” and therefore the ability of SeH to trigger a need for a fixed PET scanner is unknown.
- The methodology has no provision whereby a mobile PET provider can demonstrate its need to “convert” to a fixed scanner. Unlike other technologies, such as cardiac catheterization and previously MRI, there is no pathway for a mobile PET site to trigger a need for a fixed PET scanner. Moreover, given the limited availability of the mobile service at SeH, it is doubtful that such a provision would be helpful in demonstrating the need for a fixed scanner.
- While the number of mobile PET scanners has doubled in the last few years, neither of the most recently approved mobile scanners has proposed serving Robeson County, but the applicants have focused their host sites in the western part of the state. The most recently approved mobile PET scanner is also under appeal, which will delay the implementation of that capacity for some time. While service areas for mobile PET scanners include the entire state, SeH is served by Alliance Imaging II, which, from a practical perspective, predominately serves the eastern part of the state. As shown in Table 17F-2, that scanner is utilized at 168 percent.

Since it is unlikely that the standard methodology will generate a need for a fixed PET scanner in the near future, SeH is petitioning for a special need for a dedicated fixed PET scanner in HSA V, designated for

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<sup>3</sup> While SeH projects that its second linear accelerator will be fully utilized by the third project year, 2022, that would result in a need determination under the standard methodology in the 2023 SMFP, resulting in the development of a fixed PET scanner no sooner than 2025.

Robeson County. The reasons SeH believes it needs a fixed PET scanner to serve its patients are discussed below.

### **Limitations of the mobile service**

SeH appreciates the availability of the mobile PET service and believes it is an important part of providing PET services across the state, particularly in rural counties that may not be able to support a full-time fixed PET scanner. However, as with any mobile service, the mobile PET scanner at SeH significantly limits the patients that can be treated within their home county, based on the following issues.

1. Limited schedule and availability

As noted above, the mobile PET is on site on Monday mornings, with nine scheduled scans and one emergency scan available. While that would seem to provide a scheduled capacity of 468 scans (9 x 52 = 468), the practical capacity is actually less than that for a few reasons. First, throughout the year, many holidays fall on a Monday. Given the busy schedule of the mobile scanner, there is no opportunity for “make up” days; the capacity of those holidays is simply lost. In addition, a significant portion of scans—estimated at 15 percent currently—cannot be completed as scheduled due to patients either failing to show up for their scheduled appointment or failing to comply with requirements to abstain from eating or drinking (NPO) for six hours prior to their scheduled appointment. Despite being reminded multiple times that the precision of the test depended on the patient not eating or drinking, patients too often show up reporting that they “*only* had a Little Debbie and a Mountain Dew” when they woke up that morning, which clearly means that they cannot have a PET scan that morning. While these issues likely occur for other providers, since the mobile scanner is on site for less than six hours, there is not time to reschedule the patient later in the day or later in the week and those available times go unused. Currently, the mobile PET schedule is regularly 100 percent booked; however, the actual number of completed scans is 80 percent or less because of these issues.

SeH has requested additional time from the mobile vendor on several occasions; however, the vendor has not been able to provide additional days or times, likely due to its high utilization noted above. The referring physicians also indicate that the ideal schedule would involve several days per week, particularly for oncology patients, so they can receive a scan within a few days of their initial diagnosis. Given the nature of the mobile service and the limited number of mobile scanners in the state, SeH cannot accommodate the needs of these physicians and patients with a mobile service.

Given the limited availability, SeH is currently unable to accommodate any patient other than oncology patients. As a result, patients with cardiac or neurological conditions that might benefit from a PET scan cannot have a scan in Robeson County. The need for PET for non-oncologic conditions is discussed in more detail below.

2. Distance to nearest fixed provider

As anyone who has experienced cancer or had a loved one diagnosed with the disease understands, getting a confirmation of its stage and treatment options is of paramount importance in dealing with the physiological and emotional impact of the disease. To help patients deal with these issues, SeH is committed to getting a PET scan scheduled for every patient diagnosed with PET-appropriate cancer within five days of his or her diagnosis. Due to the lack of a fixed PET scanner at SeH, this commitment often results in referring patients outside the county to another provider, usually one with a fixed PET scanner with more schedule availability.

According to data from the Healthcare Planning and Certificate of Need Section, in FY 2017, the last year of data currently available in its database, fewer than one-half the PET scans provided to Robeson County residents were performed in the county. The following table shows that hundreds of patients traveled a significant distance for a PET scan, with the highest number traveling to Chapel Hill, a distance of more than 120 miles and approximately two hours one-way drive time.

**Table 1: 2017 Top Six Counties Where Robeson County Patients Received a PET Scan**

<i>County</i>	<i>2017 PET Patients</i>	<i>Percent of 2017 Total</i>	<i>One-Way Miles from SeH</i>
Robeson	185	41.2%	--
Orange	86	19.2%	136
Cumberland	78	17.4%	42
Durham	51	11.4%	127
Scotland	24	5.3%	33
Mecklenburg	11	2.4%	121
Other Counties*	14	3.1%	--
<b>Total</b>	<b>449</b>	<b>100.0%</b>	<b>--</b>

Source: Healthcare Planning and CON Section database

\*Other Counties include Wake, New Hanover, Catawba and Randolph (listed in descending order).

While some outmigration for services is expected, the fact that more than one-half the PET patients from Robeson County must leave the county for care indicates a barrier to access exists for the service. Of note, three of the top six patient destinations for PET scans are more than 120 miles away—one way. As discussed in detail below, this barrier has also resulted in a lower proportion of Robeson County residents receiving a PET scan.

### 3. Incompatibility with other PET scans

Given the number of patients that are referred out of the county for a PET scan, this creates another issue with patients seeking a second PET scan, which is often used to assess the effectiveness of their treatment. While there is no particular issue with the quality of the PET scan provided by the mobile equipment at SeH, the image produced by it is different from that produced on other PET scanners with different technology. The benefit of a PET scan (performed now nearly universally as a combined PET/CT scan) compared to other types of diagnostic imaging is its ability to merge the detailed anatomical image of a CT scan with the biological scan produced by the PET image, enabling more precise diagnosis. However, when PET scans are produced on different types of PET scanners, it is often impossible to ensure an accurate comparison between the two scans, which is essential in cancer diagnosis and treatment in particular. In recent years, this issue has resulted in patients having multiple scans, including one at another provider to confirm an initial diagnosis, then a second scan prior to beginning treatment at SeH to ensure that the post-treatment scan can be appropriately compared with the initial scan. For cancer patients, many of whom will be undergoing radiation treatment for their tumor, the exposure to even more radiation in an additional PET scan is suboptimal, yet anxious patients often choose to have an initial scan out of the county rather than waiting until the next time the mobile unit at SeH is on site. The development of a fixed PET scanner in Robeson County would resolve this issue.

#### **Need for a Fixed PET Scanner**

SeH recognizes that the challenges of providing a service using a mobile scanner that is only on site on a part time basis are not unique to Robeson County. However, it does believe that the need in HSA V and particularly in Robeson County is substantial compared to other counties across the state, including the potential volume of PET scans, use of PET for non-oncologic scans, and the unique characteristics of the Robeson County population.

#### Fixed PET scanners by HSA

As described above, the initial deployment of fixed PET scanners across the state occurred by HSA, then at hospitals with open heart surgery across the state. While this methodology was effective at expanding geographic access broadly in the state, it resulted in a lack of fixed PET scanners in some parts, including HSA V. As shown in the following table, HSA V has the second lowest ratio of fixed PET scanners per 1,000,000 residents in the state.



**Table 2: Fixed PET Scanners per Million by HSA per Proposed 2020 SMFP**

<i>Health Service Area</i>	<i>Fixed PET Scanners</i>	<i>2020 Population*</i>	<i>Fixed PET Scanners per 1 Million</i>
I	2	1,494,376	1.34
V	3	1,497,092	2.00
VI	3	1,443,917	2.08
III	7	2,304,663	3.04
IV	8	2,174,504	3.68
II	7	1,732,453	4.04
Statewide	30	10,647,005	2.82

\*Per NC Office of State Budget and Management, December 2018 projections, accessed July 2019.

HSA V has the second lowest ratio of fixed PET scanners per one million residents, significantly below the statewide ratio and just over one-half the ratio in HSA II. While SeH is not advocating statewide planning for fixed PET scanners based on population ratios, this analysis is helpful in understanding the access issues for the population of the region. Further, while the populations of HSAs II, III and IV may be higher than those of HSAs I, V and VI, the more populous HSAs are smaller geographically; that is, they cover less area than HSAs I, V and VI. SeH believes that this is an important consideration, as patients already must travel longer distances in HSAs I, V and VI. The lower number of fixed PET scanners covering a larger geography places an even greater burden on these residents.

It should also be noted that among the counties that do have a fixed PET scanner, three of them have smaller populations than Robeson County, and all of them would be a similar distance to another fixed PET scanner as Robeson residents—except they all have fixed PET scanners in the county.

**Table 3: Population of Smaller Counties with Fixed PET Scanners**

<i>County</i>	<i>2017 Population</i>	<i>Miles to Next Closest Fixed PET Scanner</i>
Robeson	132,606	42
Craven	102,578	43
Moore	97,264	42
Nash	93,991	44

Sources: NC OSBM, Google Maps

### Potential PET volume

In FY 2018, SeH provided 267 PET scans using its mobile service. This volume significantly understates the need for PET scans in Robeson County for several reasons, some of which are discussed previously. First, the goal at the Gibson Cancer Center is to schedule all patients for a PET scan within five days of their cancer diagnosis. While SeH believes this is best for its patients, it results in many patients being referred to other providers. SeH recently converted its electronic medical record, and referral data for the previous

system is no longer available; however, the analysis below demonstrates the number of potential oncology PET scans generated at SeH. Next, given demographic and cultural issues present in Robeson County (described below), patients often eschew referrals to unfamiliar physicians or facilities. This practice can result in patients going without a PET scan, even if it is warranted, just because it is not available at SeH, where patients are familiar with the facility, staff and physicians. Finally, these scans were only performed on oncology patients—the limited capacity of the mobile service did not permit any referrals for other types of scans, which are also needed.

*Oncology*

The first step in assessing the potential volume of oncology PET scans at SeH involves examining the number of analytic cancer cases at SeH's Gibson Cancer Center. These are cases for which initial diagnosis or treatment occurred at SeH, and therefore does not include recurrent cases or metastatic disease.

**Table 4: Analytic Cancer Cases at SeH**

	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>CAGR*</b>
Total Analytic Cancer Cases	395	412	444	6.0%
PET-Appropriate Cancer Cases	392	404	434	5.2%

\*Compound Annual Growth Rate

As shown, SeH has experienced substantial growth in the number of PET-appropriate cancer cases it treats. Moreover, this growth has occurred despite multiple major catastrophic incidents that SRMC experienced in the past few years, including a fire at the Gibson Cancer Center in 2015, which resulted in a loss of operations for some service for nearly one year. Following the recovery from that event, Hurricane Matthew severely impacted the area in 2016, then Hurricane Florence caused catastrophic flooding in September 2018, again affecting SRMC's ability to offer healthcare services, resulting in several periods in which many healthcare services were unavailable during which patients were referred or transferred to other facilities for care. Each of these events not only impacted SeH and its ability to offer healthcare services, but they also created long-lasting hardships for SeH staff and their family members. In consideration of the impact on the utilization of its services due to these three catastrophic events, the complexity involved with shifting patients to other facilities for treatment, and SeH's ability to bounce back each time to continue delivering high-quality healthcare services to the community, SeH believes that its historical growth trend is remarkable and demonstrates a need in the community that will continue to grow. To that point, the section below regarding adverse effects on the population if the petition is not approved demonstrates the health disparities present in the Robeson County population, including for cancer.

While final data for FY 2018 are still being abstracted and have not yet been reported to the cancer registry, preliminary data indicate that SeH will exceed 500 accessions. This is an important statistic, as it will qualify SeH has a "Comprehensive Community Cancer Center" as recognized by the American College of Surgeons' Commission on Cancer. SeH is already accredited as a "Community Cancer Center" with the

Commission on Cancer, but the addition of “Comprehensive” to the status recognizes larger cancer treatment programs. In North Carolina, there are 17 programs with a designation of “Comprehensive Community Cancer Center” or higher (i.e. “Integrated” or “Academic” designations); all but one of them operates a fixed PET scanner at their facility. Clearly SeH needs access to a fixed PET scanner in the county to support its high quality, accredited cancer program.

Assuming that the number of PET-appropriate cases in Table 4 represents the minimum number of oncology PET scans that could be expected at SeH, that number indicates that many more PET scans are needed in the area than are currently being provided. Moreover, for the vast majority of cancer sites that are PET-appropriate, the typical process involves at least two PET scans: one initial and one follow-up during or post treatment. Thus, the total number of oncology PET scans that should be provided at SeH is approximately 868, more than three times the number of scans provided in FY 2018. If the historical growth rate in cancer cases at the Gibson Cancer Center continues, it would expect to treat nearly 600 cancer patients by 2023, which would result in as many as 1,200 PET scans for oncology patients alone.

SeH also examined the number of patients from Robeson County having a PET scan anywhere in the state. While this number is more useful than the number of patients having a scan at SeH, given the limitations of the mobile unit, it still does not account for patients who leave the state<sup>4</sup> or who cannot travel out of the county and forgo the scan. According to data collected and aggregated by the Healthcare Planning and Certificate of Need Section, in 2017, the following number of Robeson County residents had PET scans in North Carolina, both in and out of the county.

**Table 5: Robeson County Resident PET Scans in 2017**

<i>Category</i>	<i>2017</i>
In-County	185
Out-of-County	264
<b>Total</b>	<b>449</b>
<b>% Out-of-County</b>	<b>58.8%</b>

Source: Healthcare Planning and CON Section database

As shown, more than one-half Robeson County residents had to travel out of the county for a PET scan. Please note that these data show the number of PET patients and do not reflect the number of PET scans they had, which, as noted above, is often more than one per patient.

SeH also compared the PET patient use rate for Robeson County to the statewide use rate. Based on data from 2017, the latest year currently available, SeH calculated the following use rates:

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<sup>4</sup> Given its proximity to the South Carolina state line, there is a possibility that some patients travel into that state, where the nearest fixed PET scanner is less than one hour away. PET patient origin data are not publicly reported in South Carolina.

**Table 6: 2017 PET Patient Use Rates**

<i>Geography</i>	<i>2017 PET Patients</i>	<i>2017 Population</i>	<i>Use Rate per 1,000</i>
Robeson County	449	132,231	3.40
North Carolina	49,567	10,283,255	4.82

Sources: Healthcare Planning and CON Section database; NC Office of State Budget and Management

While the difference in use may not appear significant, the Robeson County rate is actually 30 percent lower than the statewide rate. If Robeson County had the same use rate as the state, there would have been 637 patients who received a PET scan in 2017, or 42 percent more patients. Given the cancer mortality rates and demographic factors discussed below, SeH believes the lack of a fixed PET scanner in Robeson County creates a barrier to access for the service, which results in the lower use rate. Approval of the petition will help ameliorate this issue.

### *Cardiac*

As discussed in detail above, SeH is the only open heart surgery provider in the state whose patients do not have access to a fixed PET scanner within their home county. In the early 2000s, when PET scanners were being allocated first to open heart providers across the state, the expectation was that the growth in the use of PET for cardiac scans would be similar to that of oncology scans; however, the growth in cardiac scans has been slower to develop. In recent years, however, the use of PET for cardiac imaging has grown significantly, with the most recently approved fixed PET in the state reporting that cardiac PET accounted for one-half its cardiac imaging and projected it to account for one-third its overall PET utilization<sup>5</sup>. SeH currently cannot avail itself of the benefits of cardiac PET, as the mobile scanner simply cannot accommodate the additional volume that would be generated by these studies. If this petition is approved and SeH is ultimately awarded a fixed PET scanner, it already owns the generator needed to provide the radiopharmaceutical used in cardiac PET and expects to utilize the fixed PET scanner for cardiac scans. The benefit of PET for cardiac studies is described below.

As PET scanners have become more widely available, their use for cardiac patients has expanded greatly, including in North Carolina, as noted above. Due to its high diagnostic accuracy, low radiation exposure, fast image acquisition times, and suitability for ill or higher-risk patients as well as those with larger bodies, PET has established itself as a powerful tool for diagnostic cardiac imaging for the evaluation of patients with known or suspected coronary artery disease (CAD).<sup>6</sup>

Many patients with suspected or known CAD benefit from the information provided by a non-invasive cardiac imaging test. Cardiac imaging tests can provide information regarding the presence, extent, and

<sup>5</sup> See Agency Findings for Project ID # J-11659-19.

<sup>6</sup> Pan, Jonathan A. and Salerno, Michael. (2016, Sep 2). "Clinical Utility and Future Applications of PET/CT and PET/CMR in Cardiology." Diagnostics. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5039566/>

severity of CAD, estimate risk for early and late major adverse cardiac events, and assist in determining the most appropriate treatment, including medical therapy and/or coronary revascularization. Valuable information can also be provided from a normal scan result that can obviate the need for further cardiac tests, reduce unnecessary medication expenses, lead to expeditious referrals for assessment of other causes of symptoms, and relieve anxiety over potential life-threatening etiologies for symptoms.<sup>7</sup>

Although still considered the gold standard for high risk patients, historically, the diagnosis of CAD could be conclusively determined only by invasive cardiac catheterization. Over the years, advancements in imaging technology have led to tools capable of diagnosing CAD non-invasively. One such tool is PET myocardial perfusion imaging (MPI), which is now considered to be a gold standard in diagnostic cardiac imaging and definitive CAD diagnosis. The ability to diagnose chest pain and detect CAD with non-invasive PET MPI rather than invasive cardiac catheterization presents several benefits. First and foremost, the procedure is non-invasive and does not require the insertion of a catheter through a blood vessel in the patient's leg or arm into the heart. Additionally, a PET MPI is less costly and requires less time of the patient. While a cardiac catheterization procedure only takes approximately 30 minutes on average to complete, the associated time required to prep and recover/observe typically results in a patient spending at least a half day in the hospital, sometimes even requiring an overnight observation stay. A complete rest-stress PET MPI study can be accomplished from patient appointment time to completion in as little as one hour or less.

PET MPI allows accurate measurement of myocardial perfusion, absolute myocardial blood flow, and function at stress and rest in a single study session performed in approximately 30 minutes. PET perfusion images show very high diagnostic accuracy for detection of CAD.<sup>8</sup>

As noted in a joint statement issued by the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging, an important goal of imaging is to provide a high quality, appropriate test for the right patient at the right time, consistent with the Centers for Medicare and Medicaid Services (CMS) implementation of quality initiatives to assure quality healthcare with the goals of assuring effective, safe, efficient, patient-centered, equitable, and timely care. The imaging properties of PET MPI meet all of these quality goals. PET MPI is effective (high diagnostic accuracy), safe (low radiation exposure), efficient (fast image acquisition times), and patient-centered (accommodates ill or higher-risk patients as well as those with large body size), providing equitable (independent of patient characteristics and condition) and timely care.<sup>9</sup>

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<sup>7</sup> Bateman, MD, Timothy M.; Dilsizian, MD, Vasken; Beanlands, MD, Rob S.; DePuey, MD, E. Gordon et al. (2016, Aug 24) "American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET." *The Journal of Nuclear Cardiology and The Journal of Nuclear Medicine*.

Retrieved from: <http://jnm.snmjournals.org/content/early/2016/08/24/jnumed.116.180448>

<sup>8</sup> Nakazato, Ryo; Berman, Daniel S.; Alexanderson, Erick; and Slomka, Piotr. (2013, Feb 1). "Myocardial perfusion imaging with PET." *National Institutes of Health*.

Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3650901/>

<sup>9</sup> Bateman, MD, Timothy M.; Dilsizian, MD, Vasken; Beanlands, MD, Rob S.; DePuey, MD, E. Gordon et al. (2016, Aug 24) "American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular

The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging concluded that the following important properties of PET MPI according to published literature are sufficient to advance recommendations for its use in clinical practice<sup>10</sup>:

#### *High Diagnostic Accuracy*

PET MPI has both high sensitivity and specificity for diagnosis of CAD. Its high sensitivity improves recognition of multivessel CAD, and its high specificity improves recognition of the absence of multivessel CAD. Further, the combination of information from high quality perfusion images, stress function, and blood flow analysis allows for the identification of very low-risk patients that as previously noted can obviate the need for further cardiac tests, reduce unnecessary medication expenses, lead to more expeditious referrals for assessment of other causes of symptoms, and relieve anxiety over potential life-threatening etiologies for symptoms. Given its high diagnostic accuracy, PET MPI is also a valuable tool in providing a definitive diagnosis following an inconclusive echocardiogram. Absent a PET MPI, patients with an inconclusive echocardiogram would typically be referred for an invasive cardiac catheterization to definitively diagnose the presence or absence of CAD. The diagnostic accuracy of PET MPI allows for a non-invasive definitive diagnosis and in some cases can prevent unnecessary invasive cardiac catheterization.

#### *Consistent High-Quality Images*

PET MPI images have high myocardial counts, high spatial and contrast resolution, high signal-to-noise ratio, and accurate and reliable correction for the effects of tissue attenuation and scatter. Image quality is relatively unaffected by body shape or size, which distinguishes PET from all other cardiac imaging modalities. As such, PET MPI is a superior imaging tool in several ways, notably in its ability to produce high quality images with less patient movement artifacts, even in patients with a high body mass index (BMI), which can prevent an inconclusive diagnosis and potentially unnecessary treatment.

#### *Low Radiation Exposure*

A complete rest-stress PET MPI scan exposes patients to radiation doses that are well below levels known to be associated with long-term adverse effects, and low in comparison to most radiation-based cardiac assessments. This is an important safety concern for patients with established CAD, who are likely to be repetitively exposed over their lifetimes to radiation-based studies, and to younger patients with longer time frames for cancer to develop.

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Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET.” The Journal of Nuclear Cardiology and The Journal of Nuclear Medicine.

Retrieved from: <http://jnm.snmjournals.org/content/early/2016/08/24/jnumed.116.180448>

Ibid.

### *Short Acquisition Protocols*

A complete rest-stress PET MPI can be completed in less than one hour if Rb-82 is used; in comparison, a complete rest-stress using other technology (SPECT MPI) takes several hours. In addition to the obvious convenience to patients, this is an advantage for acutely ill or high-risk patients, such as those in emergency departments or acute chest pain units. The five-minute acquisition times are also helpful for those patients who find it difficult to remain still for more than a few minutes, reducing the likelihood of non-diagnostic scans due to patient motion artifact.

### *Quantification of Myocardial Blood Flow*

Blood flow quantification at rest and stress is used to measure myocardial flow reserves and allows verification of adequate stress response, further improving interpretation confidence. Regional flow reserve allows for the non-invasive detection of epicardial CAD. In the absence of epicardial CAD, flow reserve allows the assessment of microcirculatory function. The ability to quantify blood flow with PET MPI improves accuracy, risk stratification, and patient selection for interventions.

### *Strong Prognostic Power*

PET MPI, especially when myocardial blood flow data are included as discussed above, provides a high level of discrimination between different levels of risk in all patient populations for whom MPI is appropriate, including obese and non-obese people, men and women, diabetics, and patients with renal dysfunction.

As shown, PET MPI represents a highly accurate, high quality, non-invasive, and cost-saving cardiac diagnostic tool that represents a state-of-the-art, progressive approach to diagnostic cardiac imaging, which will benefit patients of SeH, who currently do not have access to this technology within their home county.

Further advancements in PET technology and clinically approved radiotracers are expected to increase the use of cardiac PET in the future. For example, sarcoidosis, which is a systemic disease with substantially increased morbidity and mortality when cardiac structures are affected, has until recently been difficult to diagnose non-invasively, especially in the identification of active inflammation. FDG<sup>11</sup> PET is an important newer tool for the identification of cardiac sarcoidosis and inflammation and exciting new studies suggest that monitoring with PET can assess whether treatment strategies are successful.<sup>12</sup>

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<sup>11</sup> FDG, <sup>18</sup>F or fluorodeoxyglucose, is the radioactive tracer typically used for oncology PET scans.

<sup>12</sup> Lundbye, MD, FACC, Justin B. and Heller, MD, PhD, FACC, Gary V. (2015, Jun 26). "Cardiovascular Positron Emission Tomography: A State of the Art and Into the Future." American College of Radiology. Retrieved from: <http://www.acc.org/latest-in-cardiology/articles/2015/06/24/14/10/cardiovascular-positron-emission-tomography-a-state-of-the-art-and-into-the-future>

Heart failure is a growing health concern with a growing older population and improved rescue therapy for those with heart failure. In recent years, it has been demonstrated that hibernating and stunned myocardium may be improved through revascularization resulting in improved left ventricular function. PET myocardial viability is an important tool used to identify patients with hibernating and/or stunned myocardium that may benefit from undergoing cardiac revascularization. By identifying appropriate areas for revascularization, there is an 80 to 85 percent change of improved function following revascularization.<sup>13</sup>

Cardiac infections are difficult to diagnose. While echocardiography is still the predominant diagnostic tool, PET imaging is gaining use for the detection of infection and inflammation related to prosthetic valves or device implantation. As such, one important new utility of PET may be the valuation of implantable cardioverter-defibrillator infections, prosthetic valve infections, or even graft infections for patients who have undergone coronary artery bypass grafting.<sup>14</sup>

Clearly, the potential for the use of PET for cardiac imaging is increasing. While the use of PET for some of these conditions may remain confined to quaternary facilities, its use for MPI is certainly appropriate for a tertiary provider like SeH. Moreover, SeH's interventional cardiologists currently have a backlog of three to four weeks for elective cardiac catheterizations. If SeH had access to a dedicated fixed PET scanner, it could offer the technology to its cardiologists and patients, particularly for MPI, which could reduce the backlog of patients awaiting elective catheterizations, many of whom may not ultimately need an interventional catheterization procedure. As a provider of comprehensive cardiac services, SeH's patients need access to this technology for cardiac PET and other indications.

#### Other Clinical Indications for PET

While PET scans are well established in diagnosing and staging cancer and more recently being utilized for cardiac imaging, there are many potential exciting advances, including different breakthrough applications for oncology and additional non-oncology applications for PET scanning, the testing of new radiotracer agents, and monitoring treatment effectiveness.

##### *Prostate Cancer*

One example of recent advances in oncology PET applications is the introduction of Axumin for use in detecting prostate cancer recurrences. Axumin (fluciclovine F18) is an FDA-approved, Medicare-covered radioactive diagnostic agent for PET imaging of men with suspected recurrence of prostate cancer after surgery or radiation. Historically, prostate cancer recurrences have been detected with a PSA test, a test that measures the amount of prostate-specific antigen in the

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<sup>13</sup> Ibid.

<sup>14</sup> Ibid.



blood, but standard body and bone scans have been unable to determine the location of the cancer until the PSA level is excessively elevated (10 to 30 or higher). In contrast, Axumin can detect recurrent disease with PSA levels less than 10 and sometimes much lower.<sup>15</sup>

The ability to locate the cancer can help guide effective therapy to a specific area of the body and limit damage to other areas of the body. Being able to detect early recurrence with an accurate scan also reveals whether or not the cancer has metastasized, and if so, to what degree. Recurrent cancer signaled only by a rising PSA is not always due to metastases. What is known as local recurrence can occur when the cancer remains in or where the prostate used to be after radiation or surgery. In this case, aggressive treatment would be unwarranted and unnecessarily toxic. Axumin PET scans, however, can accurately locate the cancer and as such, accurately determine whether the cancer is localized or if it has metastasized. A metastasis shows that the cancer has the capacity to spread, a process that ultimately leads to death in more than half of prostate cancer patients. An accurate determination that the cancer has metastasized allows physicians to implement more aggressive medical treatment protocols without fear of over-treating.<sup>16</sup>

While the Axumin scan has only thus far been approved for use in detecting prostate cancer recurrence, other applications are likely to be utilized in the future, including staging men who are newly diagnosed with Gleason scores of eight or higher or in men with elevated PSA levels above 20 and detecting early metastatic disease in lymph nodes in newly diagnosed men.<sup>17, 18</sup>

### *Neuroendocrine Tumors*

Another advancement in oncology PET is the 2016 FDA approval of Netspot, the first kit for the preparation of gallium G-68 dotatate injection, which is a radioactive diagnostic agent for PET imaging to detect rare neuroendocrine tumors (NETs) in adults and pediatric patients.<sup>19</sup> NETs are rare and develop most commonly in the lungs, appendix, small intestine, rectum, and pancreas. Many NETs start in the digestive tract, as it has more neuroendocrine cells than any other part of the body. Some tumors grow slowly while others can be very aggressive and spread to other parts of the body, most often to the liver or bone.<sup>20</sup> NETs have many treatment options, which makes it critical to accurately diagnose and delineate the extent of the disease in order to determine the most effective management. Studies have demonstrated that the use of PET scans using gallium

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<sup>15</sup> Scholz, MD, Mark. (2017, Feb 22). "Axumin PET Scans: A Breakthrough for Prostate Cancer." Retrieved from: <https://www.verywell.com/axumin-pet-scans-for-prostate-cancer-4126111>

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> Gleason scores represent a grading system that identifies how aggressive cancers are following tissue biopsy, with a score of two to four being less aggressive and a score ranging from seven to ten being more aggressive.

<sup>19</sup> See June 1, 2016 FDA News Release)

<sup>20</sup> "Molecular Imaging and Neuroendocrine Tumors Fact Sheet." Society of Nuclear Medicine and Molecular Imaging. Retrieved from: <http://snmmi.files.cms-plus.com/FileDownloads/Patients/FactSheets/MI%20and%20NETs%202016.pdf>

radiotracers are superior to the historical standard imaging technique known as In-pentetretotide imaging based on superior performance for tumor detection, lower radiation, and a two-hour completion time versus a two-day completion time.<sup>21</sup> The National Comprehensive Cancer Network (NCCN) announced in March 2017 that Netspot (GA-68 dotatate) has been included in its Clinical Practice Guidelines in the Oncology 2017 version 1 update for the evaluation of NETs. NCCN is a not-for-profit alliance of leading cancer centers in the United States that produces authoritative guidelines for oncology physicians for the treatment of all major malignancies, and for their detection, prevention, risk reduction, and associated supportive care.<sup>22</sup>

### *Alzheimer's Disease*

PET imaging continues to show promise in the area of early diagnosis of Alzheimer's disease. PET has proven to be a promising modality for detecting functional brain changes in Alzheimer's disease, identifying changes in early Alzheimer's disease, and helping to differentiate Alzheimer's disease from other causes of dementia. A meta-analysis including 119 studies evaluating the role of different modalities in the diagnosis of Alzheimer's disease showed that PET has superior diagnostic accuracy compared to other available diagnostic methods such as clinical guidelines, MRI, CT, SPECT, and biomarkers. Studies have also shown that PET has the potential to differentiate patients with Alzheimer's disease from normal subjects and patients with other causes of dementia.<sup>23</sup>

### *Movement Disorders*

PET imaging is an innovative approach for the study of movement disorders, such as Parkinson's disease. PET imaging data acquired from Parkinson's patients has revealed characteristic regional patterns associated with the motor and cognitive features of the disease. Quantification of pattern expression in individual patients can be used for diagnosis, assessment of disease severity, and evaluation of novel medical and surgical therapies. Identification of disease-specific patterns in other movement disorders that mimic Parkinson's, such as multiple system atrophy and progressive supranuclear palsy, has improved diagnostic accuracy in patients with difficult to diagnose movement disorders. Further developments of these techniques are likely to enhance the role of functional imaging in investigating underlying abnormalities and potential new therapies in these neurodegenerative diseases.<sup>24</sup>

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<sup>21</sup> Deppen, Stephen A.; Liu, Eric; Blume, Jeffrey D.; Clanton, Jeffrey et al. (2016, May). "Safety and Efficacy of 68Ga-DOTATATE PET/CT for Diagnosis, Staging, and Treatment Management of Neuroendocrine Tumors." *The Journal of Nuclear Medicine*. Retrieved from:

[https://www.snmmi.org/files/FileDownloads/Safety\\_Efficacy\\_Ga-68-DOTATATE\\_NETS.pdf](https://www.snmmi.org/files/FileDownloads/Safety_Efficacy_Ga-68-DOTATATE_NETS.pdf)

<sup>22</sup> Ibid.

<sup>23</sup> Marcus, MBBS, Charles; Mena, MD, Esther; and Subramaniam, MD, PhD, MPH, Rathan M. (2015, Feb 18). "Brain PET in the Diagnosis of Alzheimer's Disease." National Institutes of Health. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4332800/>

<sup>24</sup> Poston, MD, MS, Kathleen L. and Eidelberg, MD, David. (2010, Jan 1). "FDG PET in the Evaluation of Parkinson's Disease." National Institutes of Health.

Patients with early movement disorders often present with overlapping signs and symptoms and only later develop the specific findings needed to make a definitive diagnosis of Parkinson's, multiple system atrophy, or progressive supranuclear palsy. Accurate diagnosis is critical for patient counseling and treatment decisions. As noted above, PET imaging has successfully identified characteristic regional patterns associated with various movement disorders. In one study, PET scans from patients with different movement disorders as well as healthy subjects were compared using a special mapping technique. Maps of regional metabolic differences between patients and controls were used to create characteristic templates for each of the studied "look-alike" conditions. Disease defining features of individual scans can be visually matched to the templates allowing for the best match to be made for image classification. A reader with no expertise in PET diagnosis of movement disorders could use this computer-aided visual approach to determine a specific diagnostic category with relative accuracy. PET has proven to be a useful diagnostic tool for movement disorders including Parkinson's disease.

### *Thoracic Diseases*

Authors of a 2015 article<sup>25</sup> published in Chest Journal, the official publication of the American College of Chest Physicians, believe PET scanning will continue to evolve and will expand into imaging of inflammatory disorders. Specifically, the authors note that new clinically available PET scan radiotracers will expand PET imaging into different disease processes and that major improvements in thoracic PET/CT imaging technology will become available resulting in significant improvements in image quality, improving the evaluation of smaller lung nodules and metastases allowing for better prediction of prognosis.

The current practice of PET scanning for non-small cell lung cancer is expanding into the realm of chemotherapy monitoring; PET imaging early in the course of chemotherapy can determine the likelihood that the therapy will result in long-term benefit or not. As a result, decisions about the most appropriate course of therapy do not have to wait until anatomic imaging shows a change in the volume of a given cancer.<sup>26</sup>

PET scanning also has a role to play in nonmalignant chest diseases, such as granulomatous infection and inflammation. Several inflammatory conditions affect the chest and the inflammation they cause can be detected by PET scans. These conditions include granulomatous infections, giant cell arteritis, fibrosing mediastinitis, IgG4-related disease (formerly autoimmune pancreatitis), organizing pneumonia, granulomatosis with polyangiitis, and histiocytic processes. Ongoing research supports the use of PET scanning for inflammatory conditions, but a lack of

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Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2913894/>

<sup>25</sup> Johnson, MD, PhD, Geoffrey B.; Peller, MD, Patrick J.; Kemp, PhD, Bradley J.; and Ryu, MD, FCCP, Jay H. (2015, Jan). "Future of Thoracic PET Scanning." Chest Journal Volume 147, Issue 1. Retrieved from: [http://journal.chestnet.org/article/S0012-3692\(15\)30232-4/fulltext#](http://journal.chestnet.org/article/S0012-3692(15)30232-4/fulltext#)

<sup>26</sup> Ibid.

Medicare and Medicaid reimbursement has historically limited its impact. New and emerging approved radiotracers as well as advances in PET hardware and software are likely to advance the use of PET scanning for thoracic diseases while also improving image quality and accuracy of diagnosis.<sup>27</sup>

In summary, SeH believes there are numerous patients in Robeson County and the surrounding area that would benefit from a fixed PET scanner at the Gibson Cancer Center. In particular, SeH believes that the need identified by this petition is precisely the type of issue that should be addressed by a special need adjustment: unique circumstances that do not exist statewide and that cannot be addressed by, or wait for resolution from, the standard methodologies. When those unique circumstances exist, the SHCC has used the petition process to address these issues. Given the significant demographic and socioeconomic factors that exist in Robeson County and contribute to extreme health disparities, SeH believes the need for a fixed PET in the county warrants a special need determination from the SHCC.

### **Adverse Effects on Patients If the Petition Is not Approved**

Without the approval of this petition, oncology patients will continue to suffer from the lack of timely diagnosis and treatment planning, and cardiac patients will not have the opportunity to benefit from cardiac PET when their condition warrants. SeH has no option to expand its current capacity in terms of hours or days, much less for full-time use. Without sufficient access to PET services locally, Robeson County residents may be forced to choose between traveling 120 miles or more for treatment, as many currently do, or foregoing a PET scan altogether. Travel for this patient population is often difficult, and travel for many in Robeson County is simply not possible. The nearly 40 SeH primary care or specialist providers distributed throughout Robeson County report a total of 15,000 patient “no shows” annually, strongly indicating the difficulty patients with limited transportation and financial resources have accessing care even in their home county. Even assuming that transportation is available for traveling out of the county, most must take at least one day off work, and the lost wages for most of these patients is just one more burden the citizens of one of the poorest counties in the state must bear at a time they are literally fighting for their lives.

According to the National Cancer Institute (NCI), cancer disparities among population groups typically include differences in incidence rates, prevalence (all existing cases), mortality rates, morbidity (cancer-related health complications), survivorships, burden of cancer or related health conditions, screening rates, and stage of diagnosis. These disparities are thought to reflect the interconnection between population health factors and reported health outcomes.

Unfortunately, Robeson County exhibits high levels of health disparity. Dignity Health and Truven Health created the nation’s first standardized Community Health Need Index (CNI) to identify the severity of health disparity for every ZIP code in the U.S. based on multiple social and economic factors known to

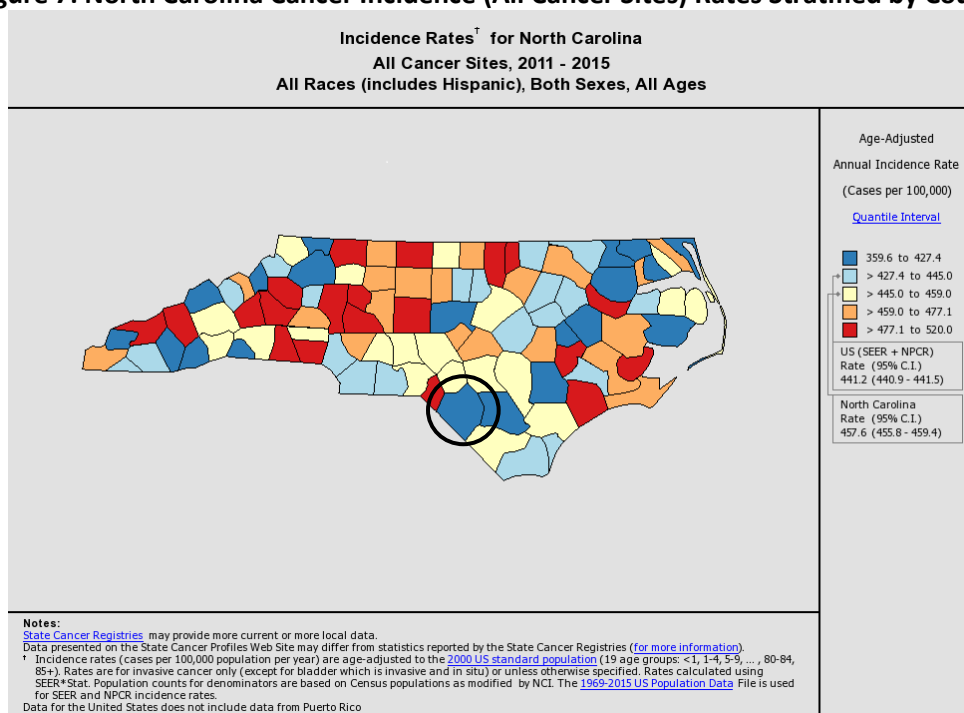
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<sup>27</sup> Ibid.

limit healthcare access. Indicator scores are obtained for the areas of income, culture, education, insurance, and housing and a barrier score of 1.0 (low need) to 5.0 (high need) is applied. Robeson County received a CNI score of 4.7 indicating a high community health need, with many communities in the county scoring a 4.8 or higher<sup>28</sup>. Further, out of the 100 North Carolina counties, Robeson County ranked last (100th) in both the 2019 health factors and the 2019 health outcomes County Health Rankings<sup>29</sup>.

In 2015, the State Center for Health Statistics found cancer to be the second leading cause of death in Robeson County. According to the American Cancer Society 2010-2014 Cancer Incidence Rates by County report, Robeson County has a higher incidence rate of prostate, colon/rectum, and lung cancer than North Carolina as whole<sup>30</sup>. Interestingly, while Robeson County ranks in the lower quantile in North Carolina for cancer incidence rates (all cancer sites) (See Figure 4), it is among the highest in the state for cancer mortality rates (See Figure 5) suggesting there are unmet diagnosis and treatment needs for this population<sup>31</sup>. The unique demographic and socioeconomic attributes present in Robeson County exacerbate the need for a fixed PET scanner in the county.

**Figure 7: North Carolina Cancer Incidence (All Cancer Sites) Rates Stratified by County**



Source: National Cancer Institute. State Cancer Profiles.

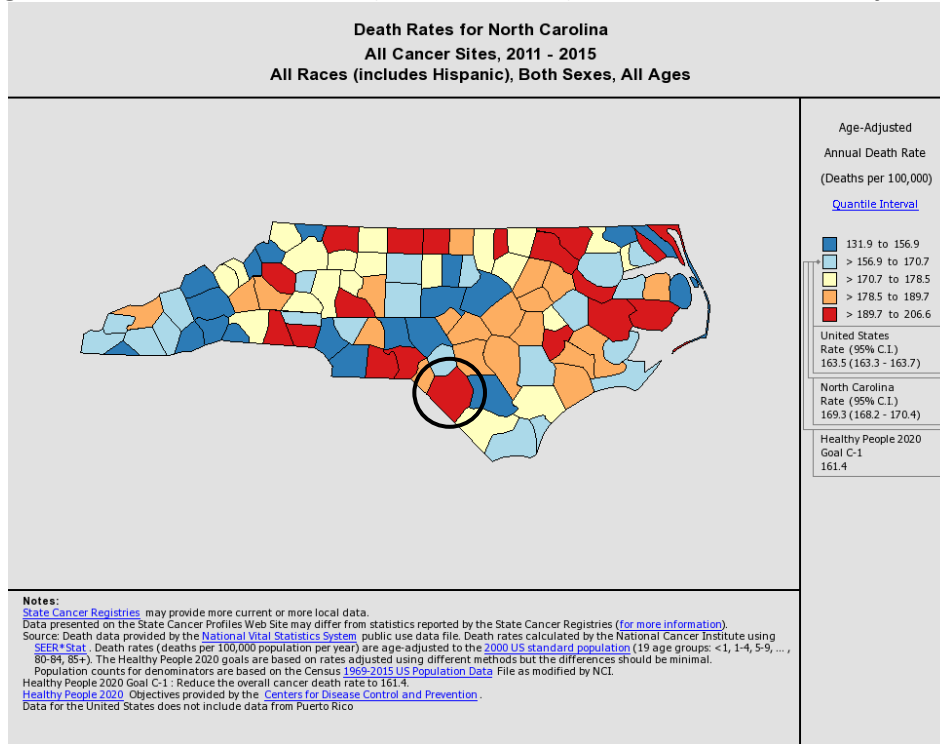
28 Dignity and Truven Health Community Need Index, Robeson County.

29 Robert Wood Johnson Foundation, 2019 County Health Rankings.

30 American Cancer Society. *Cancer Facts & Figures 2015*. Atlanta: American Cancer Society; 2015.

31 National Cancer Institute. State Cancer Profiles: North Carolina Counties, All Ages, Both Sexes, All Cancer Sites.

**Figure 8: North Carolina Cancer (All Cancer Sites) Death Rates Stratified by County**



Source: National Cancer Institute. State Cancer Profiles.

In addition to statistics related to cancer, another important statistic to consider related to the need for a fixed PET is death rates from heart disease. The presence of the open heart program at SRMC has contributed to lower death rates for county residents. At the time the SHCC first granted a special need adjustment that allowed SRMC to develop its open heart program, Robeson County’s age-adjusted heart disease death rate was 358.3. Based on 2017 data, Robeson’s death rate from heart disease has decreased significantly to 216.5, but it is still the 7<sup>th</sup> highest death rate from heart disease among North Carolina counties. Despite overall improvements in rates, Robeson County continues to experience heart disease death rates that are significantly above those of other counties with open heart programs, as well as the North Carolina rate overall.

Not unexpectedly, most of the counties in the state where comprehensive providers of cardiac services, including open heart surgery, are present also have the lowest heart disease death rates. However, despite improvements, Robeson County is not among those counties. In fact, as shown in the following table, Robeson County continues to have a higher death rate from heart disease compared to the state overall and is the highest among counties with open heart providers.

**Table 9: Age-Adjusted Heart Disease Death Rates  
Among Counties with Open Heart Providers**

<i>County</i>	<i>Age-Adjusted Death Rate 2013-2017</i>
Robeson	216.5
Cumberland	186.9
Gaston	183.9
Catawba	169.0
Pitt	167.6
Craven	166.7
Cabarrus	159.0
Forsyth	146.7
New Hanover	146.5
Buncombe	143.3
Guilford	138.2
Moore	136.9
Durham	130.7
Mecklenburg	129.9
Wake	120.3
Orange	112.7
<b>North Carolina</b>	<b>159.8</b>

Source: State Center for Health Statistics, accessed July 2019.

Statistically, Robeson County’s heart disease death rate is more than two standard deviations above the mean rate for these counties, is 35 percent higher than the statewide rate, is more than 15 percent higher than the next highest county and is more than 90 percent higher the lowest county (Orange). Despite availability of open heart surgery at SRMC, as well as the hospital’s ongoing efforts to improve access via heart disease screening programs, community education and outreach, and reduced time to clinic appointments, the county clearly continues to need improved access to services that can improve outcomes for Robeson County residents with heart disease, such as cardiac PET.

Robeson County is a federally designated healthcare professional shortage area and is recognized as a medically underserved area by the U.S. Department of Health and Human Services. The county is majority-minority with 41.3 percent American Indian and Alaskan Native and 23.9 percent Black persons (See Table 10), with the highest percentage of minority residents within the state at 68.8 percent.

**Table 10: Robeson County Race Profiles as compared to North Carolina.**

<i>Race</i>	<i>Robeson County % of Total</i>	<i>North Carolina % of Total</i>
White	31.2%	70.8%
Black	23.9%	22.2%
American Indian and Alaskan Native	41.3%	1.6%
Asian	0.7%	3.1%
Hispanic	0.2%	0.1%
Other	2.7%	2.2%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

U.S. Census Bureau 2017 Population Estimates.

Minority populations are more likely to be poor and medically underserved and demonstrate a higher disease burden when compared to non-minority populations. As highlighted in the table above, one characteristic of the Robeson County population that is strictly unique among all North Carolina counties is the high percentage of American Indians and Alaskan Natives (AI/AN) that reside in this area, particularly in Robeson County. This fact is significant in that, according to the *American Journal of Public Health*, there is a “substantial burden of disease borne by American Indian and Alaska Native people” and “overall, non-Hispanic AI/AN people have almost a 50% higher death rate than non-Hispanic White people...with diabetes, intentional and unintentional injury, and chronic liver disease taking a particularly devastating toll.”<sup>32</sup>

Further, the *CA: A Cancer Journal for Clinicians* for the American Cancer Society reported the relative risk of death after a cancer diagnosis is 33 percent higher in black patients than in white patients and 51 percent higher in AI/AN patients than white patients in their Cancer Statistics 2018 publication<sup>33</sup>. These statistics mean that in North Carolina, minority group residents are more likely to die from cancer and related conditions than the majority group residents.

In addition to the unique demographics, socioeconomic factors also explain the compromised health status of residents within Robeson County. Common risk factors associated with a higher incidence of preventable cancer and heart disease include: tobacco use, sun exposure, radiation exposure, chemicals and other substances, alcohol, poor diet, lack of physical activity and being overweight.

According to the CDC, the following socioeconomic factors correlate to health disparities:

- Access to Health Care Services
  - Racial and ethnic minorities are less likely to have health insurance

<sup>32</sup> Bauer, U.E., & Plescia, M. (2014, June). Addressing Disparities in the Health of American Indian and Alaska Native People: The Importance of Improved Public Health Data. *American Journal of Public Health*. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4035867/>

<sup>33</sup> Siegel, R. L., Miller, K. D., & Jemal, A. (2018, January 04). Cancer Statistics, 2018. *CA: A Cancer Journal for Clinicians*, 68(1). Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21442>



- Lower income levels can prevent access and utilization of health services
  - Language barriers
  - Lack of transportation<sup>34</sup>
  - Inability to take time off to see a doctor
  - Inability to pay for services
- Behaviors
  - The lower the income,
    - the more likely to smoke
    - the more likely to eat unhealthy food
    - the less likely to engage in physical activity
    - the more likely to engage in risky sexual activity
- Social and Built Environments
  - Lower income populations have less access to quality objects such as sidewalks, transportation, playgrounds, and parks
  - Rural residents are more likely to be poor than people who live in cities
- Exposure to Carcinogens
  - Those that live in close exposure to carcinogens are at a higher risk of getting cancer. Certain carcinogen contributors in communities include:
    - Smelters
    - Foundries
    - Chemical factories
    - Coal mines

As such, income and education levels can be a reliable predictor of many lifestyle behaviors and health indicators. Robeson County's 2010 per capita income ranked 99<sup>th</sup> out of 100 counties in North Carolina – \$15,321 per capita. This drastic difference in income levels demonstrates the unique characteristics of the residents in Robeson County. Moreover, according to the 2016 American Community Survey (ACS) and the Small Area Income and Poverty Estimates (SAIPE), 27.8 percent of Robeson County residents are living below the poverty level, compared to an average of 15.4 percent of North Carolina residents. As a result, Robeson County residents are more likely to smoke, be overweight, and lead a sedentary lifestyle – all risk factors for developing preventable cancers and heart disease.

Moreover, Robeson County residents display cultural beliefs and behaviors that influence their care. The rural isolation along with the large minority populations in the county contribute to a trust factor that is unique to these populations; residents are more likely to stay within their home county or with their primary provider than migrate to outside facilities for treatment. This coupled with the lack of availability of the mobile PET scanner creates a unique situation in this vulnerable community.

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<sup>34</sup> Community Health Needs Assessment. Robeson County Health Department, Southeastern Health, Healthy Robeson Task Force. 2014. The 2014 CHNA identified transportation as one of the top five leading factors affecting families seeking medical treatment.

## **Alternatives Considered**

If the adjusted need determination is not approved, SeH will continue to provide PET services through a mobile vendor. While SeH is grateful for its availability, the lack of a full-time, fixed PET scanner in Robeson County is detrimental to patients with cancer, heart disease and other conditions that can benefit from PET technology.

SeH currently does not see any other alternatives outside of the status quo or for the SHCC to approve the request for an additional dedicated fixed PET scanner in HSA V, designated for Robeson County, to meet the needs of area patients.

## **EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION**

As discussed previously, Robeson County has no fixed PET scanner. As a result, more than one-half of residents having a PET scan leave the county for care. In addition, statistics show that many more patients from the county should have a PET scan, but do not, likely because of a lack of local access. Of the counties that are contiguous to Robeson, only one (Cumberland) has a fixed PET scanner and one (Scotland) has a part-time mobile scanner. All the rest, including Bladen, Columbus, Hoke and Dillon (SC) have no PET service. Further, HSA V has one of the lowest ratios of PET scanners per million population compared to other HSAs; the last fixed PET scanner approved in HSA V was in 2003.

While there are fixed PET scanners with available capacity, the highest number of residents leaving the county for a PET scan travel over 120 miles one way to access care. Moreover, as described previously, having a PET scan at one facility and a second at another do not allow for quality comparisons between images due to differences in technology. As a result, patients must either have additional scans to ensure the images are comparable, or they must travel for all their scans, which increases the burden on the patient.

## **EVIDENCE OF CONSISTENCY WITH THE THREE BASIC PRINCIPLES**

SeH believes the petition is consistent with the three basic principles: safety and quality, access, and value.

### Safety and Quality

Quality and safety are clearly enhanced through the addition of a dedicated fixed PET scanner in Robeson County. Under the status quo, patients may need multiple PET scans performed to ensure that they receive a timely diagnosis and staging, but that subsequent scans are appropriate comparable. This duplication in scans has occurred for patients of Gibson Cancer Center and is certainly suboptimal from both a safety and quality of care perspective. Many of the patients served by SeH are reluctant or unable to travel to other providers outside the county to access PET services, and therefore either delay the

procedure or forego it altogether. Given the volume of oncology and cardiology patients at SeH, access to a full-time fixed PET scanner is essential for a quality comprehensive oncology and cardiology program.

Further, the patient population in Robeson County has higher mortality rates than other areas of the state. With difficulties traveling out of the county for care, combined with distrust of unknown providers and facilities, the lack of a fixed PET scanner is particularly harmful to residents of the area.

### Access

A dedicated fixed PET scanner is needed to provide sufficient access for SeH patients. SeH is the only open heart provider in the state without a fixed PET scanner in the county, and the mobile unit has insufficient capacity for any cardiac studies. Each year, hundreds of oncology patients are referred out of the county to other providers, the most utilized of which is over 120 miles away—one way. A fixed PET scanner in Robeson County will enable SeH to better serve these patients and potentially reduce the number of patients that leave Robeson County for care or that may forgo care due to the current barriers. SeH provides a significant percentage of its services to minority and underserved populations. Minority populations need sufficient access to PET services as they are at an increased risk to develop cancer and heart disease, two leading indications for PET. Further, there are increased socioeconomic challenges with their care such as lack of funds to seek treatment outside of their home town or inadequate transportation. For this reason, PET services must be available to patients of all demographics and socioeconomic status affording them the same access to safe and effective diagnostic imaging technology.

### Value

This petition also promotes value. While the mobile service is certainly better than no service at all, the cost per scan is significantly higher than it would be with a fixed PET scanner, which can spread the cost over more patients. For patients currently leaving the county for a PET scan, the costs associated with taking time off work and traveling for their procedure are real, but do not add anything to the quality of the process. In addition, the lack of sufficient local access may mean patients choose to go without a PET scan and instead rely on other, less effective imaging studies, which could lead to suboptimal treatments and outcomes.

The proposed petition will provide HSA V and Robeson County with additional dedicated fixed PET capacity to meet the needs of area patients and ensure health equity across the state. Southeastern Health appreciates your careful consideration of this petition. Please let us know if we can assist the Council, its committees, and the staff during the process.

Thank you.