

**PETITION OF
NEO PET, LLC
FOR AN ADJUSTED NEED DETERMINATION IN THE
2011 STATE MEDICAL FACILITIES PLAN FOR
MOBILE POSITRON EMISSION TOMOGRAPHY SCANNERS
IN THE WEST PLANNING REGION**

AUGUST 2, 2010

I. INTRODUCTION AND IDENTITY OF PETITIONER

neo pet, llc (“neo pet”) respectfully submits this Petition requesting an adjustment to the mobile Positron Emission Tomography (“PET”) scanner need determination contained in the Draft 2011 State Medical Facilities Plan (“SMFP”). All page references in this Petition are to the .pdf version of the Draft 2011 SMFP.

neo pet is an Ohio limited liability company that has provided fixed and mobile PET/CT scanners to hospitals and other health care providers for over ten years. neo pet has worked with Womack Army Medical Center over the past two years to provide mobile PET/CT services at Fort Bragg. Through its ongoing relationship with Womack Army Medical Center, neo pet has learned about North Carolina and its healthcare systems. In speaking with family and friends living in North Carolina as well as with physicians and hospital administrators, neo pet gained a respect and understanding of North Carolina’s healthcare system and Certificate of Need process.

II. STATEMENT OF REQUESTED CHANGE

Chapter 9 of the Draft 2011 SMFP states that there is no need for any additional mobile dedicated PET scanners anywhere in the State.¹

neo pet requests that the need determination in the 2011 SMFP be adjusted to reflect a need for one (1) mobile dedicated PET scanner for the west mobile PET scanner planning region of this State (HSAs I, II, and III). This Petition does not request a change with respect to any need determination for fixed dedicated PET scanners or the east mobile PET scanner planning region.

Approval of this Petition will provide any eligible applicant, including the sole mobile PET provider in North Carolina, Alliance Health Care Services, LLC (“Alliance”), with the opportunity to submit a competitive Certificate of Need application proposing the best plan for providing additional mobile PET services to patients of western North Carolina.

¹ Draft 2011 SMFP at 152.

III. REASONS FOR THE PROPOSED CHANGE

A. Western North Carolina Rural Hospitals Are Underserved and Patients of Western North Carolina Lack Access to PET Services

There is currently only one mobile PET scanner (the "Scanner") operating in the west mobile PET scanner planning region. The Scanner is operated by Alliance. As of September 30, 2009, the Scanner served 14 hospitals in the west mobile PET scanner planning region. However, on June 15, 2010, the Division of Health Service Regulation granted Alliance a Declaratory Ruling which identified 18 host sites for the Scanner. With 18 sites to be served, each site would average less than two days of service per month. The current schedule for the Scanner makes it difficult for any new hospitals to obtain service on the Scanner.

This limited service can become even more limited if a hospital's day for the Scanner is a Monday or Friday and recognized holidays fall on such days, because the Scanner does not operate on recognized holidays. Furthermore, many hospitals are limited to service for a ½ day every other weekend and most hospitals receive service on one weekday every other week or less. Only having service on the weekend can be difficult for patients to accommodate into their schedules and when a patient cannot find transportation on the day of service, the patient must either travel a long distance or wait two weeks for the service to return.

neo pet has performed an informal survey of some of the current hospitals that utilize the Scanner. The hospitals have reported that they would like to receive additional PET services – for example, weekly service (instead of only twice a month) or weekday service (instead of weekend only) – and that they would utilize the additional PET services if provided.

Currently, many of the surveyed hospitals have to refer patients each week to a facility with a fixed PET scanner, in order to ensure that the patients receive their scans in a timely manner. These referrals arise because physicians ordering PET scans for diagnostic purposes will not wait an extended period for the Scanner to return to the hospital. Instead, patients must travel between 45 and 90 minutes to a site that has a fixed PET scanner. The problem is exacerbated if a physician proposes to use PET scans for initial or subsequent treatment planning or monitoring of a current treatment plan. In that case, the scheduled day(s) for the Scanner at the hospital may not accommodate the treatment schedule, and thus the patient would be forced to travel again to another hospital (and the traveling could be for multiple scans), or worse, the physician and the patient might opt to use a modality that is not as effective for the purpose as a PET scan. neo pet's survey of current hospitals using the Scanner reflects that physicians in North Carolina use PET services for more than just diagnosis.

It can be difficult for patients who are ill to travel through the western part of North Carolina along the mountainous roads, particularly during inclement weather. These referrals to other hospitals can also be time-consuming and expensive for the patients if the PET services are being used as treatment management (rather than diagnosis only) due to the multiple scans.

For these reasons, neo pet believes that western North Carolina patients are not being served well by the existing inventory of PET scanners. A new mobile scanner is needed in this area to give these patients timely access to technology that is the emerging standard of care.

B. The Existing Mobile Scanner for Western North Carolina Is Over Capacity

The Scanner is currently operating *above the capacity* set forth in the Draft 2011 SMFP for mobile PET scanners. The Draft 2011 SMFP states that “capacity” for a mobile PET scanner is 2,600 procedures per year. For the year ended September 30, 2009, Alliance reported that the Scanner had performed 2,821 procedures, which is approximately 109% of the Scanner’s capacity. Furthermore, in the year ended September 30, 2008, Alliance reported the Scanner performed 3,196 procedures, which is approximately 123% of the Scanner’s capacity. Therefore, for the past two fiscal years, the Scanner has operated at well in excess of the capacity defined in the SMFP.

C. Methodology for Mobile PET Scanner Need Determination

1. No Existing Methodology for Mobile PET Scanners

The Draft 2011 SMFP does not provide *any* methodology for determining need for an additional mobile PET scanner; the methodology is limited to fixed dedicated PET scanners.²

2. If a Need Methodology Similar to the Fixed PET Scanner Methodology Had Been Applied, There Would Have Been a Need Determination in the 2009 SMFP

The standard methodology used to determine need for fixed dedicated PET scanners results in a need determination when a provider reports utilization of a scanner in excess of 80% of the defined capacity of 3,000 procedures.³ If a similar methodology were applied to mobile PET scanners, allowing for the lower defined capacity for mobile PET scanners, a need would be identified if a mobile PET scanner’s utilization exceeded

² Draft 2011 SMFP at 151-52.

³ *Id.*

80% of the mobile capacity, or 2,080 procedures.⁴ The Scanner's utilization has exceeded 2,080 procedures in each of the last *three* fiscal years.⁵

Even if no allowance were made for the fact that fixed and mobile scanners have different defined capacities, the Scanner would have triggered a need determination in each of the 2009, 2010 and 2011 SMFPs, because in each of those years, the utilization of the Scanner exceeded 2,400 procedures (80% x 3,000).⁶

D. Statement of Adverse Effects on the Population of the Affected Area if There Is No Adjusted Need Determination

The potential adverse effects to the population of the west mobile PET scanner planning region are that as PET usage increases, based both on clinical evidence supporting its use in new contexts, and on payor coverage of additional services, the access of patients to what is becoming the standard of care for many cancers will decline. A greater number of patients will be competing for time on a single scanner, and forced either to settle for a less effective modality or to travel long distances.

E. Statement of Alternatives to the Proposed Adjustment that Were Considered and Found Not Feasible

The alternatives considered by neo pet were (1) to seek an adjusted need determination, or (2) to do nothing and wait for a need determination in a future SMFP. Waiting for a need determination in a future SMFP does not address the needs of patients in the western part of the State in the next few years. As demonstrated by the Scanner's above-capacity utilization and the increase in the number of hospitals on its schedule, hospitals and patients are going to get less time in the coming years on the Scanner if a need adjustment is not approved. Furthermore, because of the lack of a methodology for need determinations for mobile PET scanners in the SMFP, there will not be a need determination for mobile PET scanners until either an adjustment is approved or a methodology is proposed, which would require physicians and patients to continue to have unequal access to PET services until action is taken.

IV. THE REQUESTED ADJUSTMENT WILL NOT RESULT IN UNNECESSARY DUPLICATION

neo pet realizes that there are fixed PET scanners in HSAs I, II and III that are not operating at capacity. However, neo pet believes that an additional mobile PET scanner would be unlikely to affect the utilization of the existing fixed scanners significantly, because many of the patients that will use the new mobile PET scanner will be patients who would not otherwise have had *any* access to PET technology.

⁴ 2,600 x 80% = 2,080.

⁵ Draft 2011 SMFP at 154. In Fiscal Year 2007, Alliance reported 2,558 procedures; in Fiscal Year 2008, Alliance reported 3,196 procedures; and in Fiscal Year 2009, Alliance reported 2,821 procedures.

⁶ See Note 5, above.

Furthermore, the Scanner is already operating at above-capacity, and as it continues to add hospitals to its schedule, there is less capacity available for hospitals that are already using the Scanner and no capacity for hospitals that do not currently offer mobile PET services. Therefore, this additional mobile PET scanner would not duplicate a health resource that is currently available to hospitals in the western part of the State.

V. THE REQUESTED ADJUSTMENT IS CONSISTENT WITH THE THREE BASIC PRINCIPLES OF THE STATE MEDICAL FACILITIES PLAN

A. Safety and Quality

PET is a major diagnostic imaging modality used predominantly in determining the presence and severity of cancers, neurological conditions, and cardiovascular disease. It is currently the most effective way to check for cancer recurrences, and it offers significant advantages over other forms of imaging such as CT or MRI scans in detecting disease in many patients. PET is considered particularly effective in identifying whether cancer is present or not, if it has spread, if it is responding to treatment, and if a person is cancer-free after treatment. In addition, the manner in which PET operates has significant implications in diagnosing Alzheimer's disease, Parkinson's disease, epilepsy and other neurological conditions, because it can vividly illustrate areas where brain activity differs from the norm. Furthermore, due to PET's ability to measure both blood flow (perfusion) and metabolic rate within the heart, physicians using PET scans can pinpoint areas of decreased blood flow, such as those with blockages, and differentiate living muscle from damaged muscle that has inadequate blood flow (myocardial viability), which is particularly important in patients who have had previous myocardial infarction (heart attack) and who are being considered for a procedure such as angioplasty or coronary artery bypass surgery.⁷

A PET procedure is painless, noninvasive and safe, and can replace several other testing procedures with a single exam often at reduced radiation levels and cost.⁸

Furthermore, as was acknowledged when the need determination was found for the Scanner in 2002, there is not any difference in the quality of PET scans performed on a fixed dedicated PET scanner or a mobile dedicated PET scanner.⁹

In summation, PET/CT is generally safe for most patients and increases the quality of the services provided to patients by allowing earlier detection of cancer and other diseases and more precise treatment.

⁷ The foregoing paragraph is taken from the SNM Resource Center, About Nuclear Medicine, What is PET available at <http://interactive.snm.org/index.cfm?PageID=972> (last visited July 29, 2010).

⁸ *Id.*

⁹ See, e.g., Agency Report regarding Technology Petition-4 (from Catawba Memorial Hospital and Frye Regional Medical Center), Positron Emission Tomography (PET) Scanner Petition related to the Draft 2002 SMFP.

B. Access

neo pet strongly believes that adding a mobile PET scanner will increase the access of rural western North Carolinians to PET services, which is one the key purposes of the Certificate of Need Statute.¹⁰

C. Value

By increasing patients' access to PET scanners, many potential cancers will be found to be benign while other cancers will be identified earlier; both outcomes will likely result in treatments that are less expensive for the patient and have a higher rate of success. In addition, if a provider other than Alliance is selected to provide mobile PET services, the effect of competition may help to lower the overall cost of providing mobile PET services.

[Signature Page to Follow]

¹⁰ N.C. Gen. Stat. § 131E-175(3a) (“That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.”)

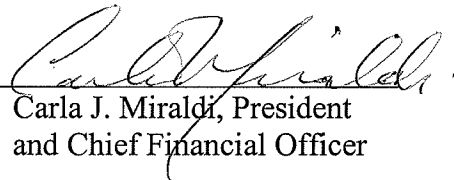
VI. CONCLUSION

For the foregoing reasons, neo pet respectfully requests that the need determination for mobile PET scanners in the Draft 2011 SMFP be modified to reflect a need for one (1) mobile PET scanner to serve the west mobile PET scanner planning region (HSAs I, II and III).

This the 2nd day of August, 2010.

neo pet, llc

By: _____


Carla J. Miraldi, President
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