

**Technology and Equipment Committee
Agency Report
Petition to Add Need Determination for
One Mobile Positron Emission Tomography (PET) Scanner in the
2021 State Medical Facilities Plan**

Petitioner:

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Request:

DMS Health Technologies, a Digirad Company, requests an adjusted need determination for one additional mobile positron emission tomography (PET) scanner to provide statewide coverage and service in the *2021 State Medical Facilities Plan (SMFP)*.

Background Information:

Chapter Two of the SMFP Provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The SMFP annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The SMFP does not have a methodology to project need for additional mobile PET scanners. Without a methodology, the basic principles of the SMFP are the guidelines used when determining the need for an additional scanner. Inclusion of a need determination for additional mobile PET scanners is by the summer petition process. Any provider may apply for the CON to acquire the mobile PET scanner, if a need determination is placed in the SMFP. The service area for mobile PET scanners is statewide (as defined in the SMFP).

DMS Health Technologies submitted a petition for an adjusted need determination for a mobile PET scanner for statewide coverage for the following reasons: 1) there is a need for additional capacity; 2) there is a need for an alternate provider; and 3) there are current limitations in scheduling and viability of mobile PET services.

Analysis/Implications:

DMS Technologies seeks to provide mobile PET services in North Carolina. They have operations in other states throughout the United States and offer experience in the mobile diagnostic industry. The state of North Carolina currently has mobile PET utilization provided by Alliance Healthcare, Insight Imaging and Novant Health. Insight and Novant each hold a CON for one mobile PET scanner. Alliance HealthCare has CONs for two mobile PET scanners. Novant’s and Alliance’s scanners are in utilization, while Insight’s is not operational yet. The Proposed 2021 SMFP reported that the three operational mobile PET scanners performed scans at 38 sites throughout the state. The Novant Health Forsyth Medical Center mobile PET scanner is restricted as to where it can provide services; it currently performs scans at six locations owned by Novant Health or a related entity. Alliance I and Alliance II mobile PET scanners perform scans at the remaining 32 locations in the state.

According to the SMFP, there has been a statewide increase in PET utilization over the past five years (see Table 1). Table 1 also shows that all operating providers have had increases in the number of procedures performed during the five-year period. The Alliance II mobile, however, had one year of a decrease in procedures. Statewide there has been a 10.67% compound annual growth rate (CAGR). The SMFP considers 2,600 scans to be 100% capacity. The Proposed 2021 SMFP shows that the Alliance I and II mobile PET scanners are operating at 143% and 153% of capacity, respectively. The Novant mobile PET scanner is operating at 80% capacity.

Table 1: Service Area and Statewide Trends in Mobile PET Procedures, Data Years 2015 - 2019

Mobile PET Providers	2017 SMFP	2018 SMFP	2019 SMFP	2020 SMFP	Proposed 2021 SMFP	Total Percent of Change	CAGR
Alliance I	3,237	3,508	2,767	3,363	3,716	14.79%	3.51%
Alliance II	3,268	3,651	3,688	4,363	3,975	21.63%	5.02%
Insight Imaging Corp.	n/a	n/a	n/a	0	0	0	0
Novant Health Forsyth Medical Center	n/a	n/a	830	1,780	2,068	149.16%	57.85%
Total Mobile PET Procedures	6,505	7,159	7,285	9,506	9,759	50.02%	10.67%
Annual Change Statewide		10.05%	1.76%	30.49%	2.66%		

Source: 2016 – 2020 License Renewal Applications

Note: The data in the SMFP is two years earlier than the publication year of the SMFP.

However, with no methodology for mobile PET scanners, there is no predetermined way to calculate the future needs for additional mobile PET scanners. Using the mobile PET scanner

utilization in the Proposed 2021 SMFP and including Part 1 of the fixed PET Scanner methodology in the SMFP, there is support for an additional mobile PET scanner. Currently, there are four approved scanners. Using the threshold of 2,600 procedures, the average utilization would be 106.57% per scanner (Table 17F-2, Proposed 2021 SMFP). This calculation includes the approved scanner that is not yet in operation and assigns it no utilization. Once this fourth scanner is placed into service, the average utilization per scanner will undoubtedly increase.

The Petition refers to the need for an alternate provider. If an adjusted need determination is approved, any person may apply, not just the petitioner. Each application must be reviewed against the statutory and regulatory review criteria independently and, to be approved, the Agency must determine that the application is conforming or conforming as conditioned to all statutory and regulatory review criteria. If there is more than one application, the Agency will also conduct a comparative analysis to determine which application is the most effective alternative to meet the need. Competition or access to a new or alternate provider is a comparative factor that has been used in a competitive review for the comparative analysis. The Petition also refers to quality of equipment, limitations and schedule availability for mobile PET scanner services. The Agency does not have statutory authority to regulate the terms of service agreements between providers and vendors.

Agency Recommendation:

The Agency acknowledges there is no need methodology for mobile PET scanners in the Proposed 2021 SMFP. However, in consideration of the above, the Agency recognizes the state has sufficient mobile PET utilization to support an additional mobile PET scanner. Given available information submitted by the August 12, 2020 deadline and in consideration of factors discussed above, the Agency recommends approval of the petition to include an adjusted need determination for a mobile PET scanner with a statewide service area in the 2021 SMFP.