

Petition for Adjusted Need Determination for One Additional Mobile PET Scanner to Provide Statewide Coverage and Services

PETITIONER

DMS Health Technologies, a Digirad Company

1351 Page Drive South

Suite 300

Fargo, ND 58103

Matthew Hoover

Sr. Manager, Market Development

717.350.2509

STATEMENT OF REQUESTED ADJUSTMENT

DMS Health Technologies, a Digirad Company respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination in the *2021 State Medical Facilities Plan (2021 SMFP)* for additional dedicated mobile PET scanners to provide statewide coverage.

EXECUTIVE SUMMARY

DMS Health currently provides mobile PET services throughout the entirety of the United States. With over 40 years of expertise and experience in the mobile diagnostic imaging industry, we are one of the oldest and most widely used mobile vendors in the market. Given our background and the current, limited number of mobile diagnostic imaging vendors providing services in North Carolina, we would like to provide facilities and patients with a choice in who they use for mobile PET/CT services.

Key Findings:

In summary, the state of North Carolina needs to address the lack of competition in the mobile diagnostic imaging space, regardless of modality. DMS Health would like to see the ability for healthy competition within this market and provide facilities and patients a choice for who provides the imaging services. DMS Health recommends the addition of mobile PET/CT scanners in 2021.

- We have heard from facilities that their current mobile provider is using older, outdated technology. This is a disservice to the North Carolina community.
- We have spoken with multiple facilities within North Carolina who would like to utilize DMS Health as a provider of mobile PET/CT imaging services but are, in a sense, handcuffed to their current mobile imaging provider due to lack of mobile organizations that hold a CON. They fear retaliation from their current mobile PET provider if they were to discover that they were looking to utilize another mobile imaging company.
- Until North Carolina allows healthy competition to take place, facilities have no other options but to accept one of two mobile imaging services. Introduction of more mobile organizations into NC will drive competition, lower costs to healthcare facilities and patients, allow more individuals access to the high-

quality imaging that they deserve, and force incumbent vendors to provide better equipment, technology, increased frequency of services provided.

- As advancements in healthcare continue, many facilities are left without the option of having a mobile PET scanner on-site. Not only does this restrict their ability to treat patients, it also creates a scenario where it is difficult to start this service line. Without a mobile PET/CT service to help start the service line and establish volumes and business case, facilities may face unnecessary challenges when purchasing a fixed scanner and starting a successful PET imaging service line from the ground up.
- Many of the patients who receive PET scans are cancer patients (over 95%). These patients already have enough stress with their current circumstances and having to travel to a location that is distant from their home is simply wrong. If they can see their oncologist and receive treatments close to home, why must we put the burden of extensive travel on them?

BACKGROUND

DMS Health Technologies, a Digirad Company is based out of Fargo, ND and has been providing mobile diagnostic imaging services since 1972. We are accredited by the Joint Commission, are the only ISO 9001 Certified mobile imaging organization, as well as holding many other accreditations.

DMS Health provides MRI, CT, PET/CT, nuclear medicine, ultrasound, bone densitometry, and 2D and 3D mammography throughout the entirety of the United States and Canada. Our current fleet of mobile diagnostic imaging equipment is from a wide variety of Original Equipment Manufacturers (OEMs) that include but are not limited to: GE, Siemens, Toshiba, Canon, Philips, Digirad, Hologic and more. We are proud to offer facilities with many different choices for equipment makes and models; each facility has the option to choose the correct level of technology for their facilities needs. DMS Health is consistently upgrading and updating our fleet of mobile diagnostic imaging equipment to ensure that facilities have access to the latest advancements in patient care.

DMS Health prides itself on working closely with facilities to address their needs. During the past 3 years, we have helped our mobile PET/CT customers grow their businesses through the addition of newly approved imaging agents, business development / educational activities with physicians, appropriate use criteria and marketing efforts. In 2018, we were able to assist our partner facilities to grow their mobile PET/CT volumes over 10% nationwide, equating to thousands of lives being positively impacted by our services.

We offer flexible service schedules, competitive pricing and high-quality service. We believe residents of North Carolina would benefit from our approach to mobile PET services, and we hope to work with providers in need of mobile PET services.

The basis for DMS Health Technologies, a Digirad Company's support of the need determination and the suggested additional language is detailed below.

Need for Additional Capacity

DMS Health is asking the SHCC to include additional mobile dedicated PET scanners based on the need for additional mobile PET capacity. Two of the existing mobile PET scanners have been the only two mobile PET scanners in the entire state since the original need determinations in the 2002 SMFP. In the 15 years since those scanners were allocated, PET volume has grown significantly across the state, including on the two mobile units, with only the addition of one mobile PET scanner. While most of the areas of the state that can support a fixed PET scanner already have a unit, the more rural areas of the state, or those with maturing oncology programs, may not yet be able to support a fixed scanner, but would benefit from addition access to a mobile scanner.

As shown in the 2017 and Proposed 2018 SMFP, the utilization of the two mobile scanners has increased significantly over the past five years and will continue to do so.

	<i>FY 2012</i>	<i>FY 2013</i>	<i>FY 2014</i>	<i>FY 2015</i>	<i>FY 2016</i>
Total Procedures	5,571	5,791	5,870	6,505	7,159
Compound Annual Growth Rate					6.5%

In the past, the existing provider has argued that the capacity of 2,600 for mobile PET scanners shown in the SMFP is too low and that 3,000 is a more reasonable number. We agree with the SHCC that the capacity of a mobile scanner is less than a fixed scanner; however, it is clear using either capacity definition that the existing mobile PET scanners have exceeded capacity and an additional unit is needed to meet the growing need.

Similar to the petition submitted by Insight Imaging in recent years, DMS Health has also heard from prospective host sites that they would like to initiate service or increase or change the service they have from the existing provider, but have been told that no additional time is available. With some sites apparently having limited service at inconvenient times, such as one half-day every other week, service on Sunday mornings or Saturday evenings, or service days/times that change often, the need for more capacity is evident even beyond the utilization data. Additionally, the amount of half days and odd service frequencies are not up to par with the standard mobile PET services provided throughout the rest of the country, regardless of mobile imaging provider. It is clear to see that the original mobile PET CON holder is attempting to provide a minimally acceptable service in order to maximize their patients exams or revenue; a disservice to the facilities and patients that they are servicing.

Table 17F-2: PET Scanner Provider of Mobile Dedicated Scanners

Mobile Provider	Procedures	Utilization Rate
		Year 2018-2019 Procedures, 2,600 as Capacity
Alliance Imaging I	3,716	143%
Alliance Imaging II	3,975	153%
Insight Imaging Corp.*	0	0%
Novant Health Forsyth Medical Center (NHFMC)	2,068	80%
TOTAL	9,759	

**CON conditionally approved on April 29, 2019, under appeal. CON Project ID: E-011630-18*

In review of the 2021 Proposed State Medical Facilities Plan, it is evident that even with the recent addition of Insight Imaging Corp. providing mobile PET services, there will still not be enough mobile PET services available to address the current. Using the figures above ("Table 17F-2: PET Scanner Provider of

Mobile Dedicated Scanners”, found within the 2021 FSMP), the total capacity of the four (4) mobile imaging units has reached a cumulative total of 376% capacity, which averages out to be 94% utilization per mobile PET imaging system. It is important to note that within this 94% utilization rate, Insight Imaging Corp has reportedly performed zero (0) scans, which would indicate a much higher utilization rate than noted for the three (3) systems that have reported performing exams.

Using the methodology for fixed PET scanners, the +94% utilization rate would indicate the need for an additional mobile PET service. Without adding any additional sites or patients, a fifth mobile PET scanner in the state of North Carolina, may reduce the current mobile PET scanner utilization to 75.2% per mobile PET scanner, which is very close to the threshold of requiring another CON to be released for any fixed site. Adding two (2) mobile PET scanners in 2021 may lower the utilization rate to 62.6%, which would allow mobile PET providers to provide services at additional centers, helping to alleviate the burden of traveling far distances for cancer patients to receive their exam. It is our belief that the addition of one (1) mobile PET scanner is necessary and a second would be highly beneficial, especially as new imaging agents are being brought to market and national PET exam rates are rising.

Need for an Alternative Provider

DMS Health believes that the proposed need determination provides the opportunity for the approval of another provider of mobile PET services in the state. While it could be argued that the approval of a single provider for the first two mobile PET scanners in the state helped ensure the viability of the service in its early days, given the maturity of the service today, that is no longer the case. DMS Health believes that a competing provider would enhance the quality and lower the cost of the service, while also expanding access to sites that need more capacity.

While the Healthcare Planning and Certificate of Need Section may consider the need for an alternative provider as part of its review, DMS Health believes that this need might be strengthened if the SHCC were to include such language in the need determination. An alternative provider would offer the opportunity to enhance competition, improve quality and lower the cost of the service, as well as to provide another perspective on the service. Over the past several years, the existing provider has repeatedly opposed the need for more mobile PET capacity, even when multiple host sites have agreed that more is needed. The table below shows the existing provider’s history of opposing the development of more capacity in the state.

<i>Year</i>	<i>Action</i>	<i>Existing Provider's Response</i>
2010	Petition by a new provider for a mobile PET scanner to serve the western part of the state; support from multiple parties	Opposition to the petition
2011	Petition to change the methodology for mobile PET scanners, which would result in a need determination for two additional mobile PET scanners; support from multiple parties	Opposition to the petition
2012	Statement in <i>Proposed 2013 SMFP</i> that no additional mobile PET scanners are needed in the state	Comment in support of the statement
2013	Petition to change the methodology for mobile PET scanners, which would lower the threshold for generating need	Opposition to the petition
	Statement in the <i>Proposed 2014 SMFP</i> that mobile PET services may not be optimally distributed in the state.	Comment in opposition to the statement
	Comment from existing host site regarding the need for more capacity and better days of service	No action
2014	Multiple petitions to change the methodology/service area for mobile PET scanners, including one from existing provider	No action on other petitions
2015	Petition proposing Policy TE-1, which allows the conversion of fixed PET scanners to mobile PET scanners under certain conditions; support from multiple parties	Opposition to the petition
	<i>Proposed 2016 SMFP</i> includes Policy TE-1, which was adopted for the <i>2015 SMFP</i> ; one provider applied under this policy	Petition to prevent further conversions pursuant to Policy TE-1

Additional pushback was also given by the existing provider in response to Insight Imaging's journey to obtaining a mobile PET CON in recent years. It is evident when reading through the commentary provided by the original mobile PET CON holder, that they are attempting to thwart any competition from your state, further demonstrating their determination to limit the amount of competition within the state.

In addition to its repeated opposition to additional mobile PET capacity, despite the pleas of existing sites without adequate service, the existing provider opposed the CON application filed under Policy TE-1 by writing comments against the application, and DMS Health understands that it even appealed the approval of that non-competitive CON application. While DMS Health understands that any party must act in its own interests, it is clear that the existing provider has consistently opposed any effort to disturb the monopoly it currently enjoys, or to ameliorate the capacity constraints experienced by its host sites and other parties.

Additional Considerations

DMS Health would like to echo the same sentiments that Insight Imaging presented in recent years. While we may be referring to the same or different facilities, our conversations and customer fears are the same. Below is an excerpt from the InSight Health Corp 2018 State Medical Facilities Plan which we believe to still be an accurate representation, based on our interactions with facilities in North Carolina.

“In light of the current monopoly for mobile PET services in the state, InSight believes that potential new providers of mobile PET services would not be competing on a level playing field with the existing provider in a competitive CON review. In particular, the only existing provider in the state has access to more detailed utilization data, knowledge of requests for additional capacity and has the ability to take punitive actions against existing host sites if they support competing applications. While this concern may seem extreme, InSight has been told by potential host sites that they are concerned about supporting an alternative provider for fear of such reprisals, such as changing days, reducing service or removing service completely. Given the existing provider’s previous actions detailed above, including appealing a non-competitive CON decision, these concerns do not appear completely unfounded.

As a result of these issues, InSight is concerned that it may be difficult for new provider applicants to secure letters of support. As the SHCC is likely aware, the CON application process, particularly for mobile services, generally requires applicants to identify the host sites and demonstrate that the host sites are willing to consider using the proposed provider. While InSight knows of no way to avoid this requirement, it would like to suggest that the SHCC consider including language in the need determination that would provide the ability for potential new providers to compete on a level playing field with the existing provider.

Specifically, the following language could be added to the need determination:

Applicants for the mobile dedicated PET scanner need determination may include letters of support from potential host sites that support multiple applicants.

InSight recognizes that neither the *SMFP* nor the Healthcare Planning and CON Section preclude applicants from including letters of support from host sites that are also supporting other applicants. As such, the inclusion of this language may seem unnecessary. However, based on the issues mentioned above, including discussions with potential host sites who have voiced this concern, InSight believes such language will reassure potential host sites—in an official document—that they are not precluded from supporting a new provider, as well as the existing provider, if they so choose. This will also lessen their concern about potential reprisals, as they will know that other host sites have the same understanding.

Finally, as suggested above, InSight believes the need determination could be strengthened if the following language were also added to the need determination:

In choosing among competing applications, priority will be given to applicants that do not currently provide mobile dedicated PET services in the state.

Mobile PET is one of the few, if not the only, regulated healthcare services in the state that is only available from one provider. Therefore, the approval of a new provider will make the service more competitive, which will benefit all areas of the state. Further, this statement is not without precedent. The *2010 SMFP* includes language about priority given to applicants for the single specialty ASC projects that include physician owners. That language was included, at least in part, out of a desire to see non-hospital applicants, who do not own as many operating rooms as hospitals, have a more equitable opportunity to be approved for the project. Similarly, InSight believes that such language would increase the likelihood that a new provider will be approved, which will enhance the competitiveness of mobile PET services in the state.”

DMS Health would also like to present another vantage point regarding the lack of mobile PET imaging in North Carolina. Below is an excerpt from Southeastern Regional Medical Center, Inc. that highlights the disservice that the original mobile PET holder has been providing at their facility. We would like to point out that this request for a fixed PET scanner using this methodology was approved.

“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. 7

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.

<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%	--
Total	449	100.0%	--

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. “

These sentiments offered by SeH and InSight Imaging are just the beginning. There is a clear need for additional mobile PET units within the state of North Carolina. Right now, facilities and patients do not have nearly enough access to the services that are needed, nor options for whom they receive the services from. Additionally, on a more human note, the SeH comments about patients having to travel great distances for a PET scan is appalling. These cancer patients are already going through a stressful time in their lives; why add unnecessary hardships by not allowing them to receive these services close to home?

Thank you for the opportunity to petition for additional mobile PET scanners in North Carolina. If DMS Health, a Digirad Company can provide any additional information, please feel free to reach out.