

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

**VIA E-MAIL**

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**Commenter**

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DMS Health Technologies, a Digirad Company (“DMS”), submitted a Petition for Adjusted Need Determination for one or more additional dedicated mobile PET scanners in the 2021 State Medical Facilities Plan.

InSight opposes the Petition. The DMS petition argues that additional mobile PET scanners are needed to promote competition for mobile PET services. However, the State Health Coordinating Council has already addressed the need for additional competition by including a need determination for a statewide mobile dedicated PET scanner in the 2018 SMFP, and approved Insight Health Corp. (“Insight”)’s Certificate of Need (“CON”) application to develop a mobile dedicated PET scanner in a competitive review. Consequently, the health planning and administrative processes are already working to resolve the issue raised by DMS, and additional need determinations should not be included in the SMFP until the previously-approved mobile PET can begin service and its effect on utilization and the market can be assessed.

**The DMS Petition for Adjusted Need Determination Relies on Outdated Information**

Initially, Insight points out that parts of the discussion and utilization data in the DMS petition are several years old and were taken directly from comments submitted to the SHCC by Insight on July 26, 2017 in support of the inclusion of a need determination for a mobile PET scanner in the Proposed 2018 SMFP (“Insight 2017 Comments”). Entire tables and paragraphs from the narrative of the Insight 2017 Comments, based on data through 2016, were apparently copied

and pasted into DMS's petition with minor edits, frequently without attribution. (Compare DMS Petition, pp. 3-6, to Attachment A, copy of Insight 2017 Comments, pp. 1-3).<sup>1</sup>.

### **The Planning and CON Review Processes have Already Addressed the Need for Additional Capacity and an Alternative Provider**

Since the Insight 2017 Comments were filed, the need determination in the Proposed 2018 SMFP for an additional mobile dedicated PET scanner was ultimately included in the final 2018 SMFP. Accordingly, a competitive CON review was conducted beginning December 1, 2018, in which four competing CON applications were submitted, two of which were from current mobile PET providers in the State or their affiliates, and two of which were submitted by prospective new mobile PET providers. DMS could have applied in that CON review but did not.

In May 2019, the Healthcare Planning and Certificate of Need Section approved the CON application submitted by Insight based on a comparative analysis of the competing applications. One of the comparative factors that resulted in Insight's approval was "Patient Access to Alternative Provider," which favors new mobile PET providers that would promote competition.

Therefore, the health planning process and the CON application review process have both recognized and addressed the need for additional mobile PET capacity and competition in North Carolina.

### **The Administrative Process is Already Working to Address the Issues DMS Raises**

The approval of Insight's mobile PET CON application (Project ID No. E-11630-18) is recognized in Table 17F-2 of the Proposed 2021 SMFP. However, it is not yet operational because the approval of the Insight mobile PET scanner was appealed by affiliates of both of the current mobile PET providers in the state.<sup>2</sup>

On February 20, 2020, the NC Office of Administrative Hearings issued its decision affirming the award of a mobile PET scanner CON to Insight. However, Mobile Imaging Partners of North Carolina, LLC, an affiliate of current provider Alliance Imaging, has appealed the decision to the North Carolina Court of Appeals, which has further delayed the issuance of a CON to Insight until the appeal is completed.

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<sup>1</sup> Also, where DMS acknowledges the Insight 2017 Comments, it inaccurately refers to them as a "petition" (see DMS Petition, p. 3). In fact, Insight filed no petition – Insight's 2017 Comments were in support of the need determination already in the Proposed 2018 SMFP. (See Attachment A)

<sup>2</sup> N.C. Gen. Stat. § 131E-187(c) requires that appeals of CON approvals must be completed before the CON may be issued.

Therefore, the previously approved Insight mobile PET scanner is progressing through the administrative process. Insight remains committed to serve the State of North Carolina with mobile PET services, and will put the new mobile PET scanner into operation as soon as it receives the CON.

### **An Adjusted Need Determination is Unnecessary**

In considering the DMS petition for an adjusted need determination for additional mobile PET scanners, it is important to recognize that the approved Insight mobile PET scanner is already nearing the end of the administrative process. In contrast, any additional mobile PET scanners that may result from a need determination in the 2021 SMFP would be subject to the same delays in the CON review process and potential administrative litigation. As a result, any additional mobile PET scanners likely would not reach the market for several more years.

Because the Insight mobile PET scanner will introduce additional capacity and competition into the market in the near term, the SHCC should not include more need determinations for mobile PET scanners at this point. Instead, the administrative appeal process should be allowed to play out and the impact on the market from the 2018 SMFP need determination should be measured before the SMFP includes additional need determinations for mobile PET scanners.

## ATTACHMENT A

### COMMENT ON A NEED DETERMINATION

#### Comment on the Need Determination for a Mobile Dedicated PET Scanner in the *2018 State Medical Facilities Plan*

##### COMMENTER

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##### COMMENT

InSight Health Corp (InSight) would like to affirm the need for a mobile dedicated PET scanner in the *2018 SMFP*. In addition, InSight would like to suggest that the SHCC consider additional language that might improve the effectiveness of the need determination.

As background, InSight, now part of the Center for Diagnostic Imaging (CDI), operates fixed and mobile PET scanners across the U.S. and Canada. Mobile imaging services are provided in 26 states, with mobile PET services available in 16 states. InSight has provided diagnostic imaging services in North Carolina for more than 20 years, where InSight has served hospitals, physicians, and military facilities.

We believe our collaborative approach to providing mobile imaging services is unique compared to others in the industry. Our goal is to partner with the host site providers, with a focus on educating physicians and patients. We provide Original Equipment Manufacturer (OEM) service for the equipment and are Joint Commission accredited. 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 if the need determination remains in the final *2018 SMFP*.

The basis for InSight's support of the need determination and the suggested additional language is detailed below.

##### **Need for Additional Capacity**

InSight agrees with the SHCC in its decision to include an additional mobile dedicated PET scanner based on the need for additional mobile PET capacity. The two 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, but no additional mobile capacity has been allocated. 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

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maturing oncology programs, may not yet be able to support a fixed scanner, but would benefit from additional 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.

	<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
<b>Compound Annual Growth Rate</b>					<b>6.5%</b>

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. InSight agrees 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.

We have 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.

**Need for an Alternative Provider**

InSight 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. InSight 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, InSight 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.

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<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

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 InSight understands that it even appealed the approval of that non-competitive CON application. While InSight 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. To help ensure that a new provider has a fair opportunity to be approved in a CON review, InSight is suggesting that additional language be added to the need determination, as detailed in the following section.

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### **Additional Considerations**

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

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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.

Thank you for the opportunity to comment on the need determination for a mobile dedicated PET scanner. If InSight can provide any additional information, please feel free to reach out to us.