



March 20, 2024

VIA EMAIL ONLY (DHSR.SMFP.Petitions-Comments@dhhs.nc.gov)

North Carolina Division of Health Service Regulation
Healthcare Planning
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Akumin's Comments Opposing Carteret Health's Petitions Regarding a Change in Methodology for Fixed PET Scanners and Regarding a Policy for Dual Function Fixed PET Scanners in Mid-Size Cancer Centers

Dear Technology and Equipment Committee Members:

Akumin, Inc. (formerly Alliance Healthcare Services) offers the following comments opposing (1) Carteret Health's ("Carteret") Petition Regarding a Change in Methodology for Fixed PET Scanners ("Methodology Petition") in the 2025 State Medical Facilities Plan ("SMFP") and (2) Carteret's Petition Regarding a Policy for Dual Function Fixed PET Scanners in Mid-Size Cancer Centers ("Policy Petition") in the 2025 SMFP. As Carteret's Methodology Petition and Policy Petition (collectively, the "Petitions") are very similar in content, Akumin is submitting one set of comments opposing both of Carteret's Petitions.

Carteret's Petitions Should be Denied for the Same Reasons Carteret's July 2023 Petition was Denied.

Carteret's Petitions seek to make changes to the 2025 SMFP that would allow a mid-sized cancer center to obtain a dual-function fixed PET scanner irrespective of the need calculated by the standard methodology in the SMFP. Those requested changes expressly include a reduction in the fixed PET scanner performance standard regulatory threshold from 2,080 scans to 1,040 scans in the third year of operation. (Methodology Petition, page 1 and Policy Petition, pages 1-2).

Carteret's current requests for a reduction in the fixed PET regulatory threshold are identical to Carteret's request in its July 2023 Special Need Petition to the SHCC for a PET Scanner/CT Simulator in HSA VI ("July 2023 Petition") wherein Carteret also requested a reduction in the fixed PET scanner regulatory threshold from 2,080 scans to 1,040 scans in the third year of operation. The Agency recommended denying the July 2023 Petition, stating "Reducing the threshold would have a statewide effect on all fixed PET scanners. This request is outside the purview of the SHCC, and in accordance with N.C.G.S. 150B, must be addressed through the rule making process." The Technology and Equipment Committee agreed with the Agency's recommendation

and the SHCC declined to make the changes sought by Carteret.

The rationale for denying Carteret's July 2023 Petition is equally applicable to Carteret's current Petitions as both Petitions seek to reduce the fixed PET scanner regulatory threshold from 2,080 to 1,040 scans. The current performance standard for fixed PET scanners at 10A NCAC 14C .3703(a)(7) requires that "applicants proposing to acquire a fixed PET scanner ... project that the ... proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project." Any change to that regulatory threshold must be addressed through the rule making process rather than in Carteret's current Petitions to the SHCC. Additionally, even if the regulatory threshold was reduced from 2,080 to 1,040 scans as requested by Carteret, Carteret still does not perform enough scans to satisfy that requirement since Carteret only performed 526 PET Scans in 2023. (Methodology Petition, page 4).

Carteret's Arguments Fail to Support the Changes Requested by its Petitions.

Carteret's Petitions advance many of the same arguments that Carteret made in its July 2023 Petition to support the requested change in methodology and/or the addition of a new policy to the 2025 SMFP, including that mobile PET scanners provide limited access and offer only one isotope, FDG. (Methodology Petition, pages 4-5, 8, 10; Policy Petition, pages 3-4, 6, 9). As it did in its July 2023 Petition, Carteret asserts in its current Petitions that its current mobile PET unit cannot provide specialized isotopes that would allow Carteret to offer brain, breast, or prostate cancer scans and therefore Carteret must refer almost half of its cancer patients who need PET scans out of the county. (Policy Petition, page 9; Methodology Petition, page 10; July 2023 Petition, page 2).

Contrary to Carteret's assertion that "mobile PET scanners are an imperfect solution", mobile PET scanners provide a viable and attractive alternative to the changes proposed to the 2025 SMFP by Carteret's Petitions. Although Carteret contends its current mobile contract (which is with Akumin) limits Carteret to 600 PET scans annually, that limit is self-imposed by Carteret. At present, Akumin's staff and mobile PET equipment has the ability to provide Carteret with 850 to 1600 scans annually. Additionally, in contrast to Carteret's representation that it can only obtain the FDG isotope, Akumin can provide Carteret with radiation therapy planning technology and multiple specialty isotopes, including the following:

RadioPharmaceutical (Isotope)	Anatomy/Disease/Tumor
Amyvid	Alzheimer's
DetectNet	Neuroendocrine
NetSpot	Neuroendocrine
Mucicix	Prostate
Locametz	Prostate
Posluma	Prostate
Pylarify	Prostate

Therefore, the barriers to access identified in Carteret's Petitions that are supposedly causing Carteret to refer over half its patients out of the county easily can be remedied through mobile PET service, whether that is through Akumin or another mobile PET provider. (Methodology Petition, pages 4 and 8).

For the foregoing reasons, Akumin respectfully requests that the Technology and Equipment Committee and the SHCC reject Carteret's Petitions and refrain from revising the fixed PET scanner standard methodology and/or including a new policy in the 2025 SMFP.

Respectfully submitted,

A handwritten signature in cursive script that reads "Tina Hair Hinshaw".

Tina Hair Hinshaw
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