

VIA EMAIL



August 7, 2024

Sandra B. Greene, DrPH, Chairperson
North Carolina State Health Coordinating Council (SHCC) &
Technology & Equipment Committee
c/o Healthcare Planning Section
NC Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

RE: Novant Health Comments Regarding Mission Health's Petition for An Adjustment to the Need Determination to add a Dedicated Cardiac PET Need Determination in HSA I

Dear Dr. Greene:

Novant Health appreciates the opportunity to comment on the recent petition filed in the development of the 2025 State Medical Facilities Plan ("SMFP") by Mission Health for an adjustment to the fixed PET scanner need determination in HSA I. Mission Health proposes to "convert" the general fixed PET scanner need determination to a "specific need determination" for a fixed dedicated cardiac PET scanner. Rather than consider the best interests of patients in the large, multi-county Health Service Area, Mission approaches the HSA I PET scanner need determination from a purely Mission-centric perspective. Acknowledging that Mission's oncology service does not need another PET scanner, Mission wants to preclude others from obtaining a general use PET scanner which might depress Mission's utilization even further. Instead, Mission proposes to "convert" the need determination to a cardiac-specific need for which only Mission could apply. See Petition, page 2. North Carolina's health planning process exists to address needs for the service area as a whole; it is not intended to meet the desires of an individual provider.

The proposed 2025 SMFP indicates a need for one additional fixed PET scanner in HSA I which currently has four approved PET scanners. North Carolina's SMFP does not contain need determinations or a need methodology for specialized PET scanners, like cardiac PET. If Mission believes there should be such a need determination and need methodology, it should file a Spring petition in 2025; now is not the appropriate time. Moreover, there is nothing to preclude Mission for applying for the need determination for a dedicated PET scanner in 2025, and proposing to use it as a cardiac PET scanner. In fact, that is exactly what Mission proposed in its 2023 CON application to acquire a second PET scanner. See Petition, page 3; see also Findings on Project I.D. No. B-12335-23 (July 26, 2023). There was no need determination for a cardiac PET scanner in the 2023 SMFP. Further, as the chart on page 5 of the Petition shows, facilities in North Carolina are using their existing PET scanners for cardiac scans. These providers either obtained their PET scanners through the need determination for general purpose PET scanners, or, in the case of Academic Medical Centers, through SMFP Policy AC-3 which exempts AMCs from need determinations under certain conditions. Either way, none of the providers who offer cardiac PET scans obtained their scanners through a need determination for cardiac PET. Thus, this Petition was not only filed at the wrong time but is also completely unnecessary.

Dr. Sandra B. Greene
August 7, 2024
Page 2

Novant Health believes the intention of the Technology and Equipment Committee (“TEC”) is to address capacity issues in the service area. As the Mission Health petition states, two of the four PET scanners in HSA I are not yet fully operational. It is difficult to ascertain the future volumes of these scanners, but it is reasonable to assume that once these scanners are fully operational, capacity will be increased at Mission Health enough to accommodate more cardiac scans on its existing unit. Novant Health disagrees with Mission Health’s assertion that approving a general use PET scanner in 2025 will dilute PET utilization and prevent the development of a cardiac PET program. An existing PET scanner can perform cardiac scans if the provider can obtain the tracer, Rb-82, which is only available with a rubidium generator. See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4566054/>. A rubidium generator can be rented on a daily/weekly/monthly basis. See, e.g., <https://cdlnuclear.com/solutions/mobile-rubidium>. There is a new tracer in Phase 3 of clinical trials for cardiac scans that does not require the generator and would make cardiac scans easier for existing PET scanners to perform. <https://pubmed.ncbi.nlm.nih.gov/32703509/>.

Novant Health is unaware of the TEC or the SHCC ever approving a “specific” need determination for a special-purpose fixed PET scanner that would effectively limit the use of the equipment and therefore access for many patients who would benefit from a general use PET scanner. Mission Health may apply along with any other applicants for the fixed PET scanner with the scope of services narrowed to cardiac services only and compete on its application’s merit in the CON review process. Mission Health’s petition is a blatant attempt to limit competition in HSA I. Novant Health has recently filed a CON application to develop a cancer-focused hospital in Asheville. If approved, this hospital would offer beneficial choice and competition, and would be an ideal site for another fixed PET scanner that could be used by any patient who is appropriate for PET imaging, not just cardiac PET imaging. Mission has opposed Novant Health’s CON application.

Novant Health supports the standard methodology for fixed PET scanners found in the Proposed 2025 SMFP which determines the need in HSA I. Mission Health’s petition does not adequately demonstrate the need for a “specific” need determination for a dedicated cardiac-only fixed PET scanner. Mission Health’s request in this petition is best addressed in the 2025 CON application and review process for the need for a fixed PET scanner in HSA I. Alternatively, Mission can file a petition in the Spring of 2025 proposing a need determination and need methodology for cardiac PET.

Novant Health respectfully requests that Mission Health’s petition be denied.

Sincerely,

DocuSigned by:

Andrea Gymer

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Andrea Gymer

Vice President, Strategic & Business Planning