

CERTIFICATE OF NEED REVIEW STANDARDS FOR
POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES
SUMMARY OF PROPOSED CHANGES

Highlights of Proposed Changes

Section 1 - Applicability

- Section 1 modified only for consistency with other CON review standards.

Section 2 - Definitions

- Definitions related to equivalency methodology removed as the department is proposing a simpler methodology for replacement and expansion based on actual scans, not equivalencies. Also, if a definition is used only in a certain section, the definition has been moved to that section to make it easier for the reader to identify the defined terms.

Section 3 – Initiation of PET Scanner Services

- Sections 3 and 4 were combined as these sections related to the initiation of a PET service, as well as requirement for mobile services and host site conversions.
- The department has NOT modified the methodology for initiation.
- The department has added language in 3(2) to allow applicants to not only contract for special services from hospitals within the same planning area but also hospital that may be near the proposed site but not within the planning area (20-mile radius of the proposed site). Currently proposed sites are limited to contracting for services within the same planning area.
- Modified the conversion methodology for host sites to fixed PET scanner service from equivalencies to scans. Proposed PET scans threshold is based on the current equivalency requirements (4,500 and 4,000) divided by the statewide average weight per scan (2.4) for host sites. After reviewing the total scans per site, the department adjusted the scan requirements to 1,700 (urban) and 1,500 (micro/rural). These numbers may need further review and adjustment.
- No changes to initiation of a mobile network in subsection 3(6); other than simplifying the language to make it easier to read.
- Subsection 7(c) applies both to new fixed PET scanner services as well to host sites that have converted from mobile to fixed services.
- Subsection 8(c) continues to allow existing host sites to change from one existing mobile provider to another provider; however, a minimum volume requirement was added at 50 scans at the applicant host site.

Section 4 – Replace Existing PET Scanner(s) or PET Scanner Service

- The replacement section will cover both the replacement of the scanner as well as replacing the existing service to a new geographical site.
- Replacement of a scanner(s) will no longer require the applicant to meet a set volume requirement. Upgrades to existing PET scanners, without the replacement of the scanner(s), will not require CON review/approval.
- Replacement of an existing PET scanner service remains the basically the same; however, the maintenance volume requirement was converted from equivalencies to scans.
- The department eliminated the provision to allow existing providers to relocate only a scanner(s) while not replacing the entire PET scanner service to a new geographical site.

Section 5 – Expand a PET Scanner Service

- Subsection (1) to expand a fixed PET scanner service remains the same requirements, but converted from equivalencies methodology to scans. Proposed PET scans threshold is based on the current equivalency requirements (5,500 and 5,000) divided by the statewide average weight per scan (2.8) for fixed sites.
- Subsection (2) to expand a mobile PET scanner network remains the same requirements, but converted from equivalencies methodology to scans. Proposed PET scans threshold is based on the current equivalency requirements (5,000 and 4,500) divided by the statewide average weight per scan (2.5) for networks.
- Subsection 5(3) is new and allows a fixed PET scanner service that has re-initiated a host site at the fixed site to expand to another fixed PET scanner if both the fixed scanner(s) and host site average enough volume to justify expansion (similar volumes as fixed site expansion).
- Language allowing fixed sites to convert to a mobile network has been removed.

Section 6 – Acquire a PET Scanner Service

- New language has been added for renewal of lease. Applicants must demonstrate the maintenance volume threshold to renew a lease.
- Subsection 6(1) is new and allows for the first acquisition of a PET scanner service without meeting the maintenance volume requirement. This provision is similar to other standards.
- Subsection 6(2) adds a scan volume requirement threshold for acquisition of a fixed or mobile PET scanner service.
- Subsection 6(3) is new and adds a scan volume requirement threshold to acquire an existing host site.
- Language allowing for the acquisition of a PET scanner from a fixed site has been removed.

Section 7 - Dedicated Research PET Scanner

- No proposed changes to requirements that must be offered by the applicant to qualify for a dedicated research PET scanner. However, the department did limit the number of dedicated research PET scanners at any one site (3), and that the site must already offer PET services.

Section 8 – Dedicated Pediatric PET Scanner

- No proposed changes to requirements that must be offered by the applicant to qualify for a dedicated pediatric PET scanner. However, the department did limit the number of dedicated pediatric PET scanners at any one site (3).

Section 9 – PEM Scanner Service

- The department is drafting requirements for this NEW section. Based on the department's research to date, the department believes language is needed for this specialized scanner similar to the language for dedicated research and pediatric PET scanners. The department will propose language for both fixed sites and possibly mobile PEM networks. Input on this specialized scanner is greatly appreciated during this review period.

Section 10 – Medicaid Participation

- No changes proposed. Modification to section is to standardize language similar to other standards on Medicaid participation requirement.

Section 11 – Project Delivery Requirements

- Simplified and reduced number of requirements that must be maintained after approval. Proposed changes focused on limiting requirements to those that are easy to identify, measurable, and have value in improving the quality of the PET scanner service.
- Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
- Added subsection (2)(d) to assure all services set forth in Section 3, subsections (1) through (4), are maintained for the life of the PET scanner service.
- Added a minimum maintenance volume requirement (500 scans), except when an applicant is proposing to replace a PET scanner.
- New subsection created (6) for dedicated pediatric scanners. Subsection (7) is being developed for PEM scanners.
- Clarified subsection (4)(a) to restrict scans from dedicated research, pediatric, and PEM scanner(s) to count towards volume requirements.

Sections 12, 13, 14, 15, and 16 – Data Commitments for Initiation of PET Scanner Services

- No changes proposed. Limited edits to wording to make methodology easier to read.

Section 17 – Inventory of PET Scanners

- No changes proposed.

Section 18 – Comparative Reviews and Planning Policies

- No changes proposed, except for required update to dates.