

MDCH Recommendations for CON Standards Scheduled for 2011 Review

Positron Emission Tomography (PET) Scanner Services Standards (Please refer to the attached MDCH staff analysis for additional details.)		
Should PET services continue to be regulated under CON?	Yes.	While PET scanners, especially mobile PET scanners, have become increasingly available, PET scanners still require large initial capital investment as well as long term operating expenditures.
Identified Issues	Recommended for Review	Comments
Consider PET standards to specifically address Positron Emission Mammography (PEM)	Yes	The Department will provide the Commission with the recommendations addressing PEM scanner technology in the standards at the March 24, 2011 CON Meeting
Consider refinement to current utilization methodology for replacement and expansion of existing PET scanners and services, respectively.	Yes	Current utilization methodology is labor intensive for existing providers to accurately collect and report to the Department for replacement, expansion and compliance requirements. Also, the current methodology offers little, if any, correlation between required volumes to initiate a PET service and volume requirements to replace an existing unit or expand a current service. Maintenance volume is the same for both fixed and mobile services, yet volume requirements are different for initiation, replacement and expansion. In addition, a review is needed of the appropriateness of the data categories used for initiation (specific cancer diagnoses, diagnostic cardiac catheterization, intractable epilepsy, and possibly front temporal dementia/Alzheimer's). Finally, consideration should be given to allowing commitment of the differential data for those who have committed cases and the 5-year period of operation of the service to which the original data was committed has elapsed (similar to open heart surgery services).
Consider simplification of equipment replacement requirements.	Yes	Existing PET services must meet set volume requirements to replace existing equipment. However, simplification of the replacement requirements with minimal to no volume requirement affords providers the opportunity to replace existing units as newer, better technology becomes available assuring patients receive the best standard of care.
Identified Issues	Recommended	Comments

	for Review?	
Consider minimum volume requirement for host sites receiving mobile PET services.	Yes	Minimum volumes for host sites are required for MRI services to assure sites receive minimum and continuous services. A minimum volume requirement is recommended for PET services to achieve a similar goal as in MRI.
Consider allowing existing host sites to relocate.	Yes	Host sites cannot relocate to a new site, even if the new site serves the same service area and offers lower operating costs. Applicants must reapply as initiating a new host site. Such a relocation provision is important if a minimum volume requirement for host sites is approved.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable, objectively measurable, and achieve major objectives of assuring affordable, quality PET services without overwhelming providers.

MDCH Staff Analysis of the PET Scanner Services Standards

Statutory Assignment

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the PET Scanner Services Standards are scheduled for review in calendar year 2011.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from four (4) organizations and is summarized as follows:

1. Jim Gilson, Beaumont Hospitals:

- Beaumont Hospitals support the overall regulations of PET Scanner services; however, has some recommendations on items that need to be addressed:
- Would like there to be a review of the weights assigned to "bed positions" due to the variances in PET camera manufacturers.
- Recommends CON regulations provide use of research PET in unanticipated downtime.
- Would like to see review of PET standards to consider making an exemption for the use of Positron Emission Mammography (PEM).

- Contends that the lack of standards or exemption from PET CON standards confines the use of PEM to research protocols and denies comprehensive breast care programs in Michigan from offering women this clinical tool.
2. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*
 - Supports the continued CON regulation.
 - Recommends neither change nor the formation of a SAC.
 3. *Meg Tipton, Spectrum Health Hospitals:*
 - Supports the continued CON regulation.
 - Recommends no change.
 - Contends that current CON standards have assured the availability of sufficient access to PET scanners to meet the needs of Michigan citizens, while enabling health care organizations to provide quality care to patients.
 4. *Tina Weatherwax Grant, Trinity Health*
 - Supports the continued CON regulation.
 - Recommends the formation of a workgroup to propose language that establishes a formal definition of “radiation therapy patient visit,” specifically regarding Section 16 (c).
 - Contends that current standards do not include a definition for radiation therapy patient, and consequently there is opportunity for undercounting and over counting in applying the standards to projects which propose expansion, replacement or initiation of a fixed PET from a mobile route.

Summary of Covered Service

The Department received no testimony for de-regulation of PET scanner services. Michigan is one of 24 states that regulate PET services within CON. In accordance with the 2009 Michigan CON Annual Survey, less than 1% of Michigan’s population received a PET scan (38,033) from the 26 units located within the 70 approved sites throughout the state.

MDCH Staff Recommendations

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various imaging standards, where applicable, and create a user-friendly format.**

MDCH Staff Recommendations - continued

- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers to replace covered equipment in a more streamlined process that assures consumer access to advance technology.**
- **Conduct departmental review related to PEM scanner technology and existing requirements. Develop, if needed, requirements that assure this technology/service is readily available where needed.**
- **Present proposed draft standards to Commission at the March 24, 2011 meeting.**