From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/19/2011 3:07 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: 7-19-11CTPublicComment.pdf

1. Name: Amy Barkholz
2. Organization: Michigan Health & Hospital Association
3. Phone: 517-886-8224
4. Email: abarkholz@mha.org
5. Standards: CT
6. Testimony:

Content-Length: 254451

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

July 19, 2011

Certificate of Need Commission
Capitol View Building
201 Townsend St.
Lansing, MI 48913

RE: Public Comments on Computed Tomography (CT) Standards
Submitted Electronically

Dear Certificate of Need Commission:

Today the Michigan Health & Hospital Association (MHA) learned for the first time of a recent change in the Centers for Medicare & Medicaid Services (CMS) policy concerning computed tomography (CT) procedures that will have a significant impact on the proposed CT standards currently under review.

Effective Jan. 1, 2011 providers are no longer allowed to charge separately for abdomen and pelvis CTs performed in one session. Under the new CMS policy these procedures are now bundled and have a new single CPT code.

Given this recent change in policy we ask that the weights in the proposed standards be adjusted to compensate for this bundling of previously separate procedures. If the weights are not adjusted then the proposed CT standards will not reflect the intended volume levels because procedures that were previously counted separately will now be counted as one.

A failure to adjust the weights of the proposed standards will have an unintended and negative impact all applicants that perform abdomen and pelvis scans. We believe this is a technical amendment to address an unforeseen policy change. Thank you for your consideration of this matter. The MHA has no further comments on the proposed standards.

Sincerely,

Amy Barkholz
General Counsel

SPENCER JOHNSON, PRESIDENT
CORPORATE HEADQUARTERS ◆ 6215 West St. Joseph Highway ◆ Lansing, Michigan 48917 ◆ (517) 323-3443 ◆ Fax (517) 323-0946
CAPITOL ADVOCACY CENTER ◆ 110 West Michigan Avenue, Suite 1200 ◆ Lansing, Michigan 48933 ◆ (517) 323-3443 ◆ Fax (517) 703-8620
www.mha.org

From: <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 1:48 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: CT
6. Testimony: This letter is formal testimony by Spectrum Health about the proposed revisions to the CON Review Standards for CT Scanners, as revised for public hearing by the CON Commission at their meeting on June 9, 2011. Spectrum Health has no objections to the most recent proposed changes to these Standards. However, we would like to point out an issue arising in the CT Standards precipitated by reimbursement changes instituted by CMS, effective January 1, 2011.

As currently written, the CT Standards refer to ôbillable proceduresö when calculating the number of ôCT equivalents,ö which is the unit of measure employed to determine eligibility of CT providers to replace or expand their CT units. Effective January 1, 2011, CMS revised their CPT codes defining ôbillable proceduresö for certain categories of body CT scans. Specifically, separate billing codes for abdominal and pelvic CT scans were eliminated and replaced with combined codes. The impact for CT providers of this ôbundlingö of billing codes is that we now can bill for one procedure, where, many times in the past, we were able to bill for two (2) procedures. The effect of this change on volume reporting for CON will be a substantial reduction in the reported number of ôbody scansö by all CT providers, without a commensurate reduction in machine usage. We have calculated the number of CT equivalents for body scans at six (6) different CT sites operated by Spectrum Health f
or the first six (6) months of 2011. The result is nearly a 30% reduction in CT equivalents for body scans, using the new CPT codes, compared with using the previous codes applied to CT utilization over the same time period. Clearly this reflects an unanticipated consequence for CON regulation resulting from a change in the reimbursement system.

Furthermore, CT providers have been put on notice that CMS intends to bundle additional currently separate CPT codes in the future. Short of revising the CT Standards annually by updating the procedure weights after the impact of CMS billing changes can be ascertained, a permanent correction needs to be instituted in the language of the Standards.

The previously unbundled set of CPT codes has been the reference point for considering CT volume requirements in discussions by both the SAC and the Commission. We suggest making a simple change to the definition of ôbillable procedureö referencing billing codes in effect prior to January 1,

Spectrum Health recognizes that this issue is not the subject of the current comment period on the CT CON Standards. Furthermore, we do not wish to delay implementation of the revised Standards by necessitating a new comment period. However, we do not believe that it was the intent of the CT SAC or the Commission to require a 30% increase in CT body scan volume to comply with the CON volume requirements. We believe that the simple definition change suggested above would correct this situation, without changing the intent or substance of the CT Standards, and could be considered a technical change to the Standards without requiring further public comment.

Spectrum Health is willing to draft a proposed definition, as described above, for consideration by the Commission at the next scheduled meeting on September 22, 2011.

7. Attachment:

From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 10:26 AM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: CT_Public_Comment_21Jul2011.pdf

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: 734-647-1163
4. Email: sszelag@umich.edu
5. Standards: CT
6. Testimony: Please see attached

Content-Length: 1731544

University of Michigan
Hospitals and Health Centers

Steven E. Szelag
Strategic Planner

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300 N. Ingalls, 4A11-3
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July 21, 2011

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Public Comments on Computed Tomography

Dear Commissioner Falahee:

The University of Michigan Health System (UMHS) would like to offer comments on the Certificate of Need (CoN) review standards for Computed Tomography (CT) Services.

UMHS strongly supports the continued regulation of CT services, and has no objections concerning the work conducted by the CT Standards Advisory Committee (SAC). However, we do have some additional comments on a recently-identified issue.

The volume calculations for determining the utilization of a CT scanner under the current (and proposed) CT Standards are based on billable CT procedures as defined in Section 2(1)(b) of the Standards. That subsection defines "billable procedure" as "…a CT procedure or set of procedures commonly billed as a single unit, and performed in Michigan." Billable procedures are used in calculating CT Equivalents (CTE's) under Section 21 of the Standards. CTE's are the measure of need for initiation, expansion, replacement, relocation, and acquisition of non-special CT scanners, and are the measure for the ongoing volume requirements.

The problem is that, effective January 1, 2011, the Centers for Medicare and Medicaid Service (CMS) began bundling groups of multiple CT CPT codes into single codes for procedures performed together greater than 95% percent of the time. The result has been a reduction in billable procedures and a reduction in the number of CTE's, which are the basis for all volume requirements under the Standards, even in cases where the utilization of the CT unit has not changed.

For example, after January 1, 2011 providers may not charge separately for abdomen and pelvis CT's performed in a single session. These procedures are now bundled as a single billable procedure and have new CPT codes that are used for all payers (including Medicare) when the CT Abdomen and CT Pelvis are rendered at the same session. Some groups of activities that counted as two separate billable procedures in 2010 now count as single billable procedure. The time required to perform the bundled studies has not changed, but the change in the calculation

of billable procedures makes it appear that there is less utilization of the scanners. We understand that there may be additional bundling of CT procedures for billing purposes in the future.

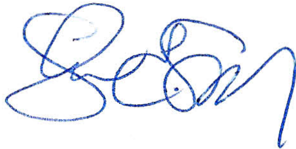
The CT SAC discussed the CMS bundling initiative; however, at the time it was unclear what the impact would be on CTEs until actual utilization data could be reviewed. UMHS has modeled CTE data utilizing the bundled CPT codes and has observed a significant decrease in reportable volume. Therefore, to avoid unintended results and to assure predictability in the application of these revised Standards, UMHS recommends that the CoN Commission add the following language to the definition of "billable procedures" in Section 2(1)(b):

> "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit AS OF DECEMBER 31, 2010, and performed in Michigan."

Allowing providers the ability to utilize CT CPT codes that were in effect on December 31, 2010 for volume purposes is consistent with the provisions the SAC assumed were in effect when it reviewed of the Standards. It will avoid any unintended CT volume accounting irregularities resulting from the changes that were recently implemented by CMS. Once the impact of the new billing policies is fully determined, further revisions to the Standards can be taken, if needed.

Thank you for according us this opportunity to address this concern. We stand ready to work with you and with the Department on these issues.

Sincerely,



Steven E. Szelag

From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/20/2011 1:11 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: KCI_PET_Public_Comments7-20-11.pdf

1. Name: Carol Christner
2. Organization: Karmanos Cancer Institute
3. Phone: (313) 578-4436
4. Email: christne@karmanos.org
5. Standards: PET
6. Testimony:

Content-Length: 1804983

BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

July 21, 2011

Mr. James B. Falahee, Jr., JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend, 7th Floor
Lansing, Michigan 48913

Re: CON Standards for PET Services

Dear Chairman Falahee,

I am writing to provide comments on the proposed changes to the Certificate of Need Review Standards for Positron Emission Tomography (PET) Scanners. The Karmanos Cancer Center very much appreciates the effort put into these revisions by the Department and commends them for making this a very open process. At the final public discussion for these standards, we expressed concerns about the section related to Positron Emission Mammography (PEM) and were very happy to see the Department incorporate some of our requests in the language they presented to the Commission in June. However, we do have a couple of additional suggestions and concerns that we would like you to consider.

PEM is a very specialized diagnostic tool used for diagnosing breast cancer. The PEM section of the standards was written to limit use of this technology to only facilities that are providing the highest level of breast cancer treatment. Although everyone was in agreement that Karmanos most definitely reaches that level of care, we find ourselves in a unique situation. Karmanos currently provides PET services to our patients through a contract with Children's Hospital of Michigan (CHM). CHM has a fixed PET scanner and has sufficient capacity to service our patients. And, because CHM is physically connected to Karmanos, it is also very convenient for our patients, while being cost effective for both facilities.

The proposed PEM language would allow Karmanos to apply for a fixed PEM unit or to become a host site on a mobile PEM route, and we are very much appreciative of the Department's changes to make that a possibility. However, we would like the Commission to consider some additional changes that would, as an alternative, allow CHM to be the applicant and CON holder for this service as well. Although we are not in a position to commit today, it is possible that it would make the most sense, from a cost and staffing perspective, for CHM to provide the PEM service to Karmanos patients since they currently provide all other PET services.

In addition, we do have concerns about references in the section to "AN APPLICANT PROPOSING TO ADD A PEM SCANNER SERVICE TO AN EXISTING PET SCANNER SERVICE." Although language further in the subsections makes accommodations for a facility that does not have an existing PET scanner service, the inconsistency causes concern. We have suggested alternative language in the attached to address this concern as well.

4100 John R
Detroit, Michigan 48201
1-800-KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org

We have shared all of this information with the Department and look forward to working with them and the Commission on these standards as they move forward in the process. As always, we thank you for your time in considering these concerns and comments and ask for your support as you review these again in September.

Respectfully,

Carol Christner

Section 9. Requirements for A POSITRON EMISSION MAMMOGRAPHY (PEM) scanner

Sec. 9. AN APPLICANT PROPOSING TO ~~ADD~~ ***INITIATE*** A PEM SCANNER SERVICE ~~TO AN EXISTING PET SCANNER SERVICE~~ SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) AN APPLICANT PROPOSING TO ~~ADD~~ ***INITIATE*** A FIXED PEM SCANNER ~~TO AN EXISTING FIXED PET SCANNER SITE~~ SHALL DEMONSTRATE THE FOLLOWING:

(A) THE APPLICANT IS CERTIFIED THROUGH THE AMERICAN COLLEGE OF RADIOLOGY (ACR) AS A BREAST IMAGING CENTER OF EXCELLENCE (BICOE) AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(B) THE APPLICANT HAS PERFORMED 1,000 PET EQUIVALENTS PER SCANNER AT THE SITE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT OR THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE.

(C) THE PROPOSED SITE CAN HAVE NO MORE THAN ONE FIXED PEM SCANNER APPROVED UNDER THIS SECTION.

(2) AN APPLICANT PROPOSING TO ADD A MOBILE PEM SCANNER TO AN EXISTING MOBILE PET SCANNER SERVICE SHALL DEMONSTRATES THE FOLLOWING:

(A) THE CENTRAL SERVICE COORDINATOR APPLICATION FOR A MOBILE PEM SCANNER SHALL BE ACCOMPANIED BY AT LEAST FIVE (5) COMPANION HOST SITE APPLICATIONS FOR INITIATION OF MOBILE PEM SCANNER SERVICES. THE PROPOSED HOST SITES HAVE NOT RECEIVED MOBILE PEM SCANNER SERVICES WITHIN THE MOST RECENT 12-MONTH PERIOD.

(B) THE APPLICANT HAS PERFORMED AN AVERAGE OF 500 PET EQUIVALENTS PER SCANNER ON THE EXISTING MOBILE PET NETWORK IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

(C) THE APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE PROPOSED HOST SITES AND CENTRAL SERVICE COORDINATOR.

(E) THE PROPOSED NETWORK CAN HAVE NO MORE THAN ONE MOBILE PEM SCANNER APPROVED UNDER THIS SECTION.

(3) AN APPLICANT~~, WHETHER AN EXISTING FIXED PET SCANNER SITE OR HOST SITE,~~ PROPOSING TO INITIATE MOBILE PEM SCANNER SERVICES AS HOST SITE SHALL DEMONSTRATE THE FOLLOWING :

(A) THE APPLICANT IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(B) THE APPLICANT HAS PERFORMED 100 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT OR THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE.

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

(4) AN APPLICANT PROPOSING TO ADD AN EXISTING PEM SCANNER HOST SITE TO AN EXISTING MOBILE PEM SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(A) THE HOST SITE HAS PERFORMED MOBILE PEM SCANNER SERVICE WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED SITE IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

Note: BOLD and Italics indicates new language added, for those of you viewing this in black and white. Otherwise red indicates new language.

From: <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 4:22 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)

1. Name: Gregory S. Dobis
2. Organization: McLaren Regional Medical Center
3. Phone: 810-342-1400
4. Email: gregd@mclaren.org
5. Standards: PET
6. Testimony: McLaren Regional Medical Center is currently building a Proton Beam Therapy (PBT) Center for the treatment of cancer patients at 4100 Beecher Road, Flint, Michigan 48532. This cancer treatment modality is the most advanced in Michigan. An integral part of this PBT center is a fixed PET/CT scanner unit.

Our goal is to establish a fixed PET/CT scanner unit in the building that houses the proton beam therapy unit.

Currently, there are two mobile PET/CT scanner host sites on the campus of McLaren Regional Medical Center campus on Mobile PET network #126. Their addresses are McLaren Regional Medical Center, 401 S. Ballenger Highway, Flint, Michigan 48532 and McLaren MRI Center, 750 S. Ballenger Highway, Flint, Michigan 48532.

Geographically, the PBT Center, McLaren Regional Medical Center, and the McLaren MRI Center buildings are all on the McLaren campus, but due to City of Flint and Flint Township requirements, they are all required to have separate addresses. Consequently, under the current and proposed CON Review Standards for PET/CT scanners, it is not possible to use the volume of the site-specific mobile PET/CT scanners to initiate a fixed PET/CT scanner service at the PBT Center. Moreover, it is not possible for McLaren to submit newly diagnosed cancer cases, cardiac catheterization data, or intractable epilepsy data in support of a new PET/CT scanner site, as the Medical Center has previously committed this volume for the initiation of Mobile PET network #126.

In theory, it would be possible to treat the PBT patients at the two mobile host sites, thus building up their volume to convert one or both mobile units to fixed units at their existing sites. However, this would be inefficient in terms of patient care and would still not allow us, under the proposed standards, to establish the fixed unit at the PBT Center.

Another theoretical alternative might be to establish a mobile PET/CT scanner host site at the PBT Center and build up the volume until it qualified for a fixed unit. However, this also is no longer an option, as the layout of the PBT Center site makes it impractical to operate a mobile unit at that location due to access issues.

An effective alternative and one technical in nature would be to allow for additional language to be added to the requirements to initiate a PET scanner service under Section 3 (4) of the ôCON Review Standards for Positron Emission Tomography Scanner Services for CON Commission Proposed Action on June 9, 2011ö. Suggested language could read The applicant shall install the fixed PET unit at the same site as the existing host site or within a 10-mile radius of the existing host site for a Metropolitan Statistical Area County or a 25-mile radius for a Rural or Metropolitan Area County. This is consistent with similar language in the MRI Standards, Section 3(2)(d).

Once the fixed site was established at the PBT Center, both mobile host sites currently on the campus of McLaren Regional Medical Center would discontinue operation.

If you need additional information or have any questions please contact Greg Dobis, Corporate Director of Planning, McLaren Health Care at gregd@mclaren.org or 810-342-1400. Thank you for your consideration

in this matter.

7. Attachment:

From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 2:30 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: SJMHSPETStd.doc

1. Name: Alice Pichan
2. Organization: St. Joseph Mercy Health System
3. Phone: 734-712-3418
4. Email: pichana@trinity-health.org
5. Standards: PET
6. Testimony:

Content-Length: 91032

SAINT JOSEPH MERCY HEALTH SYSTEM

A MEMBER OF TRINITY HEALTH

5301 East Huron River Drive
Post Office box 995
Ann Arbor, MI 48106-0995
Telephone 734-712-3456

July 20, 2011

Gay Landstrom
CON Commissioner
Health Policy Section- MDCH
201 Townsend Street
Lansing MI 48913

RE: Proposed changes in the PET Certificate of Need Standards

Dear Ms. Landstrom:

Thank you for offering the opportunity to provide input regarding proposed changes to the PET Certificate of Need Standards that are eligible for revision this year. We participated in two of the MDCH public hearings on March 14th and May 24th, as well as submitted comments in a letter to the MDCH dated March 16, 2011. We continue to have concerns regarding the proposed changes to the PET CON Standard.

PROPOSED VOLUME REQUIREMENTS FOR A MOBILE HOST TO INITIATE FIXED PET

The Saint Joseph Mercy Health System (SJMHS-AA) site at Ann Arbor has operated as a Host Site for five years with the desire to convert from a Host to a Fixed site. The site has experienced continual growth. . SJMHS-AA was listed as second highest for Host Site for both PET volume and PET Equivalent in the state for 2009, the most recent publicly released PET Equivalent data. The 2010 PET Equivalent data demonstrated an increase over 2009 and 2011 volume data also demonstrates growth over the same time period in 2010. .

We are on track to achieve the 4500 PET Eq required for conversion to a Fixed site by the end of CY2011. But the proposed change in both methodology and total PET Eq required for conversion will delay our conversion to a Fixed site by an estimated 3 years. SJMHS-AA was the second highest volume mobile host site per the most recent data. We believe that our experience is likely representative of other host sites as well.

We support the change in methodology to determine the PET Eq through the assignment of value to the CPT code. This will make the calculation easier for the Host sites as well as the MDCH. The statewide average weigh per scan of 2.4 PET Eq/patient selected by MDCH for the proposed Standard is the basis for the new requirement of 1700 patient for urban location converting from Host to Fixed. This conversion factor is a low estimate of the work performed as calculated on the current MDCH Form, if completed correctly. Please refer to the attachment for this form as submitted by SJMHS to MDCH for 2010 PET Eq. totals.

SAINT JOSEPH MERCY HEALTH SYSTEM
A MEMBER OF TRINITY HEALTH

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CONCERNS WITH THE CURRENT PET REPORTING AND EQUIVALENTS METHODOLOGY
SJMHS recognizes the value of the PET Equivalents system for purposes of exam stratification. We also acknowledge that the current system is not uniformly applied and has contributed to confusion and submission errors.

The current PET Equivalents calculation is based on "number of bed", which is related to patient's height/scan length. For example, in the table below, you can see a 5'4" patient would result in a 6 bed scan and a PET Equivalent of 2.6. (Table 1)

Table 1
Calculating PET Equivalents per the Current Standards

# of Beds	PET Eq	**Understanding the current PET Eq calculation include "Number of Bed"**
		Number of Beds on most of the manufacturers is similar and related to pt height & dx
6	2.6	An adult up to 5'3" scanned for Skull-Base to Mid-Thigh would be 6 bed positions
7	2.9	An adullt 5'4" - 5"9" scanned Skull-Base to Mid-Thigh would be 7 bed positions
8	3.2	An Adult 6"4" scanned Top of the Head to Tip of Toes would be 15 bed positions
9	3.5	
15	5.3	One manufacturer design increases the number of beds for the same patient height.

- 81% of the Hosts sites submitted an average weight PET Equivalent of less than or equal to 2.6.(see Table 2 in related spreadsheet)
- 19% of the Host sites submitted an average weight PET Equivalent between 2.7 – 3.6 (see Table 2)
- The six fixed PET sites submitted an average weight PET Equivalent of 2.93. (see Table 3 in related spreadsheet)
- The eight mobile providers submitted an average weight PET Equivalent Eq of 2.34 (see Table 4 in related spreadsheet)

An average weight less than or equal to 2.6 PET Equivalents would indicate that 100% of the exams were performed on patient less than 5'4" tall at that PET service. *This is highly improbable and the basis of our recommendation for a more realistic and standard PET equivalent value.* Therefore, we suggest the current method is not only causing reporting errors, but that the average weight for most PET services would most certainly be higher than 2.6

More than likely the MDCH selected 2.6 as the conversion factor because it was the average of the 2009 Host Site data, even though it is not a true representation of the patient population – unless all of the PET patients in 2009 were 5'4" tall or less.

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HEALTH SYSTEM
A MEMBER OF TRINITY HEALTH

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A more realistic conversion factor would be 2.93 PET Eq/patient as submitted by the six fixed PET sites in 2009, resulting in a new patient 1535 patient per year for urban sites rather than 1700 patient per year under the proposed standard.

CURRENT AND PROPOSED STANDARD FOR CHANGING MOBILE VENDOR

Recently in an effort to reduce cost, SJMHS along with other Trinity Health partners attempted to seek competitive bids for PET mobile service. We discovered that under the current and proposed PET standard that we were only able to consider moving to other mobile vendors that already had a PET CON in the state. And there are very few mobile vendors with the capacity to handle the Trinity Health patient volume. Therefore the PET standard actually limits the ability to compete for lower pricing and improvement in services.

Again, I appreciate the opportunity to provide this input. I would be happy to discuss my analysis and recommendations to you or your staff as needed. Please contact me at 734-712-3418 or 734-429-1530 if you have questions or would like additional information.

Sincerely,

Alice Pichan, M.S.
Manager, Nuclear Medicine & PET Scan
Saint Joseph Mercy Health System

From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 2:45 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: PEM-Language.pdf

1. Name: Mary Zuckerman
2. Organization: DMC and Children's Hospital of Michigan
3. Phone: 313 745-1246
4. Email: mzucke@dmc.org
5. Standards: PET
6. Testimony:

Content-Length: 203885

Mary L. Zuckerman
Chief Operating Officer

The Detroit Medical Center
Corporate Administrative Offices
3990 John R Street
Detroit, MI 48201-2403
Phone 313-745-6192
Fax 313-966-7569

July 21, 2011

Mr. James B. Falahee, Jr., JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend, 7th Floor
Lansing, Michigan 48913

Re: CON Standards for PET Services

Dear Chairman Falahee,

It is my understanding that the Commission is accepting public comment on proposed changes to the Certificate of Need Review Standards for Positron Emission Tomography (PET) Scanners. We would like to take this opportunity to commend the Department on the way they reviewed these standards and brought forward recommended changes. We are supportive of all of the changes, but do want to express one concern with the language related to Positron Emission Mammography (PEM) section.

Children's Hospital of Michigan (CHM) currently provides PET services for all of Karmanos Cancer Center's patients requiring this service. Because we are physically connected to Karmanos, this set up is not only cost effective, but also convenient for their patients. By combining CHM's existing PET service and the breast cancer care provided at Karmanos, all requirements of the proposed PEM standards are met. However, CHM and Karmanos combined cannot be the legal applicant for a CON and therefore don't quite meet the proposed requirements.

During the MDCH meetings discussing these standards we expressed this concern and received very supportive feedback from the Department and all participants. Everyone agreed that Karmanos Cancer Center should have access to PEM services. The Department incorporated some changes to allow Karmanos to qualify as the legal applicant, which was a great improvement. However, because CHM currently provides all PET services for Karmanos, and has all of the staff trained to provide PET services, it is possible that it would make the most sense for CHM to be the applicant entity and hold the CON for the PEM service, just adding it to our existing PET services.

We have worked with Karmanos to create some proposed changes to the PEM language which are attached. These changes would maintain the intended limitations on PEM to only facilities that provide the highest level of breast cancer care, while accommodating situations where facilities choose to share PET services as a way to decrease costs. We have shared this language with the Department and look forward to working with them and the Commission on these standards as they move forward in the process. We thank you for your time in considering these comments and ask for your support as you review these standards again in September.

Respectfully,

Mary L. Zuckerman
Chief Operating Officer
The Detroit Medical Center

MLZ:jc

cc: Eric Fischer
Terry Gerald

Section 9. Requirements for A POSITRON EMISSION MAMMOGRAPHY (PEM) scanner

Sec. 9. AN APPLICANT PROPOSING TO ~~ADD~~ ***INITIATE*** A PEM SCANNER SERVICE ~~TO AN EXISTING PET SCANNER SERVICE~~ SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) AN APPLICANT PROPOSING TO ~~ADD~~ ***INITIATE*** A FIXED PEM SCANNER ~~TO AN EXISTING FIXED PET SCANNER SITE~~ SHALL DEMONSTRATE THE FOLLOWING:

(A) THE APPLICANT IS CERTIFIED THROUGH THE AMERICAN COLLEGE OF RADIOLOGY (ACR) AS A BREAST IMAGING CENTER OF EXCELLENCE (BICOE) AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(B) THE APPLICANT HAS PERFORMED 1,000 PET EQUIVALENTS PER SCANNER AT THE SITE IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT OR THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE.

(C) THE PROPOSED SITE CAN HAVE NO MORE THAN ONE FIXED PEM SCANNER APPROVED UNDER THIS SECTION.

(2) AN APPLICANT PROPOSING TO ADD A MOBILE PEM SCANNER TO AN EXISTING MOBILE PET SCANNER SERVICE SHALL DEMONSTRATES THE FOLLOWING:

(A) THE CENTRAL SERVICE COORDINATOR APPLICATION FOR A MOBILE PEM SCANNER SHALL BE ACCOMPANIED BY AT LEAST FIVE (5) COMPANION HOST SITE APPLICATIONS FOR INITIATION OF MOBILE PEM SCANNER SERVICES. THE PROPOSED HOST SITES HAVE NOT RECEIVED MOBILE PEM SCANNER SERVICES WITHIN THE MOST RECENT 12-MONTH PERIOD.

(B) THE APPLICANT HAS PERFORMED AN AVERAGE OF 500 PET EQUIVALENTS PER SCANNER ON THE EXISTING MOBILE PET NETWORK IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.

(C) THE APPLICANT PROVIDES A ROUTE SCHEDULE FOR THE PROPOSED MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE PROPOSED HOST SITES AND CENTRAL SERVICE COORDINATOR.

(E) THE PROPOSED NETWORK CAN HAVE NO MORE THAN ONE MOBILE PEM SCANNER APPROVED UNDER THIS SECTION.

(3) AN APPLICANT~~, WHETHER AN EXISTING FIXED PET SCANNER SITE OR HOST SITE,~~ PROPOSING TO INITIATE MOBILE PEM SCANNER SERVICES AS HOST SITE SHALL DEMONSTRATE THE FOLLOWING :

(A) THE APPLICANT IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(B) THE APPLICANT HAS PERFORMED 100 PET EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT OR THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE.

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

(4) AN APPLICANT PROPOSING TO ADD AN EXISTING PEM SCANNER HOST SITE TO AN EXISTING MOBILE PEM SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(A) THE HOST SITE HAS PERFORMED MOBILE PEM SCANNER SERVICE WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED SITE IS CERTIFIED THROUGH THE ACR AS A BICOE SITE AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT ***OR THE APPLICANT IS PHYSICALLY CONNECTED TO AND CONTRACTS WITH A FACILITY THAT IS CERTIFIED THROUGH ACR AS A BICOE.***

(C) THE APPLICANT PROVIDES A PROPOSED ROUTE SCHEDULE FOR THE MOBILE PEM SCANNER SERVICE.

(D) THE APPLICANT PROVIDES A DRAFT CONTRACT FOR PEM SERVICES BETWEEN THE HOST SITE AND CENTRAL SERVICE COORDINATOR.

Note: BOLD and Italics indicates new language added, for those of you viewing this in black and white. Otherwise red indicates new language.

From: DoNotReply@michigan.gov <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 4:36 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)
Attachments: MSU_Sparrow_MRT_Comments7-21-11.pdf

1. Name: Melissa Cupp
2. Organization: MSU and Sparrow
3. Phone: 517-374-2703
4. Email: melissacupp@wienerassociates.com
5. Standards: MRT
6. Testimony:

Content-Length: 65992

July 21, 2011

Mr. James B. Falahee, Jr., JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend, 7th Floor
Lansing, Michigan 48913

Re: CON Standards for MRT Services

Dear Chairman Falahee,

The CON Commission charged the Department with holding a public hearing to take comments on the Certificate of Need Standards for Megavoltage Radiation Therapy (MRT) Services. We appreciate this opportunity to provide feedback on the changes proposed by the Department. Overall we are supportive of the revisions, but do have one suggested modification.

During the Department led discussion meetings on these Standards, a suggestion was made to clarify what entities qualify to commit new cancer cases toward the initiation of a new MRT service. It is clear under Section 12 of the MRT CON Standards that any existing entity that currently operates an MRT service shall not contribute its existing cancer cases to initiate any new MRT service. This is an attempt to avoid duplication of existing MRT service. It also should logically follow that no applicant should be able to use new cancer cases that are presently being treated or reported by an existing MRT service to support a new MRT service to avoid the same duplication, but the language in the Standards is less than clear that this should be the proper interpretation.

We are writing to request that the Commission amend the language proposed by the Department to add language to Section 12 of the Standards, which would clearly state that new cancer cases that are presently treated or reported by an existing MRT service cannot be used by an applicant to support a new MRT service. Suggested language is attached for Section 12(3).

Thank you for your time and consideration of this request. We ask for your support as these standards continue through the CON process.

SPARROW HEALTH SYSTEM

By: ______________________
Joseph Ruth
Its: Executive VP and COO

MICHIGAN STATE UNIVERSITY
HEALTH TEAM

By: ______________________
Richard Ward
Its: CEO

Section 12. Commitment of new cancer cases

Sec. 12. An applicant using new cancer cases to demonstrate need shall meet the following:

(1) Each entity contributing new cancer case data provides a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.

(2) The locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT service.

(3) An entity currently operating or approved to operate an MRT service shall not contribute new cancer cases to initiate any MRT service NOR SHALL NEW CANCER CASES TREATED OR REPORTED BY AN EXISTING MRT SERVICE BE USED BY AN APPLICANT TO SUPPORT A NEW MRT SERVICE.

From: <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 4:15 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)

1. Name: Gregory S. Dobis
2. Organization: McLaren Regional Medical Center
3. Phone: 810-342-1400
4. Email: gregd@mclaren.org
5. Standards: MRT
6. Testimony: McLaren Regional Medical Center is currently building a Proton Beam Therapy (PBT) Center for the treatment of cancer patients at 4100 Beecher Road, Flint, Michigan 48532. This cancer treatment modality is the most advanced in Michigan. An integral part of this PBT center is a fixed PET/CT scanner unit.

Our goal is to establish a fixed PET/CT scanner unit in the building that houses the proton beam therapy unit.

Currently, there are two mobile PET/CT scanner host sites on the campus of McLaren Regional Medical Center campus on Mobile PET network #126. Their addresses are McLaren Regional Medical Center, 401 S. Ballenger Highway, Flint, Michigan 48532 and McLaren MRI Center, 750 S. Ballenger Highway, Flint, Michigan 48532.

Geographically, the PBT Center, McLaren Regional Medical Center, and the McLaren MRI Center buildings are all on the McLaren campus, but due to City of Flint and Flint Township requirements, they are all required to have separate addresses. Consequently, under the current and proposed CON Review Standards for PET/CT scanners, it is not possible to use the volume of the site-specific mobile PET/CT scanners to initiate a fixed PET/CT scanner service at the PBT Center. Moreover, it is not possible for McLaren to submit newly diagnosed cancer cases, cardiac catheterization data, or intractable epilepsy data in support of a new PET/CT scanner site, as the Medical Center has previously committed this volume for the initiation of Mobile PET network #126.

In theory, it would be possible to treat the PBT patients at the two mobile host sites, thus building up their volume to convert one or both mobile units to fixed units at their existing sites. However, this would be inefficient in terms of patient care and would still not allow us, under the proposed standards, to establish the fixed unit at the PBT Center.

Another theoretical alternative might be to establish a mobile PET/CT scanner host site at the PBT Center and build up the volume until it qualified for a fixed unit. However, this also is no longer an option, as the layout of the PBT Center site makes it impractical to operate a mobile unit at that location due to access issues.

An effective alternative and one technical in nature would be to allow for additional language to be added to the requirements to initiate a PET scanner service under Section 3 (4) of the ôCON Review Standards for Positron Emission Tomography Scanner Services for CON Commission Proposed Action on June 9, 2011ö. Suggested language could read The applicant shall install the fixed PET unit at the same site as the existing host site or within a 10-mile radius of the existing host site for a Metropolitan Statistical Area County or a 25-mile radius for a Rural or Metropolitan Area County. This is consistent with similar language in the MRI Standards, Section 3(2)(d).

Once the fixed site was established at the PBT Center, both mobile host sites currently on the campus of McLaren Regional Medical Center would discontinue operation.

If you need additional information or have any questions please contact Greg Dobis, Corporate Director of Planning, McLaren Health Care at gregd@mclaren.org or 810-342-1400. Thank you for your consideration

in this matter.

7. Attachment:

From: <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 3:11 PM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: MRT
6. Testimony: This is formal testimony by Spectrum Health about the proposed revisions to the CON Review Standards for Radiation Therapy (MRT) Services, as approved for public hearing by the CON Commission at their meeting on June 9, 2011. Spectrum Health appreciates the opportunity to comment on these Standards.

In general, Spectrum Health supports the proposed revisions to the CON Review Standards for MRT Services. MDCH did an excellent job of leading discussions resulting in consensus regarding revisions to the CON Review Standards. We are especially supportive of the changes to the requirements for MRT units to be used primarily for research purposes. Spectrum Health continues to oppose efforts to eliminate minimum volume requirements for replacement of existing machines for all CON-covered services. We are convinced that there must be minimum volume of procedures, greater than 1, below which it cannot be argued that the unit is needed. We are willing to consider minimum volumes requirements for replacement which are substantially below the initiation volume requirement. Spectrum Health appreciates the willingness of the Commission and the Department to consider these concerns.

We appreciate the opportunity to comment on these pending CON Review Standards.

7. Attachment:

From: <DoNotReply@michigan.gov>
To: <mdch-CONwebteam@michigan.gov>
Date: 7/21/2011 9:16 AM
Subject: July 14, 2011 Public Hearing for Computed Tomography (CT) Services Written Testimony (ContentID - 196938)

1. Name: Tricia L. Sommer
2. Organization: MidMichigan Health
3. Phone: 989-839-3271
4. Email: tricia.sommer@midmichigan.org
5. Standards: MRT
6. Testimony: We would recommend that Section 14(2)(C)be modified to reflect current CMS guidelines.
Current CMS guidelines do not require that a radiation oncologist be immediately available.
Rather, page 72000,Section XII.A.1.a of the Federal Register/Vol. 75, No.226 published November 24, 2010 states "For services furnished on a hospitalÆs
main campus, we finalized a
modification of our proposed definition
of æædirect supervisionÆÆ in new paragraph
(a)(1)(iv)(A) of ° 410.27 that allowed for
the supervisory physician or
nonphysician practitioner to be
anywhere on the hospital campus.
Therefore, as of CY 2010, direct
supervision on the hospital or CAH
campus or in an on-campus PBD meant
that ææthe supervisory physician or
nonphysician practitioner must be
present on the same campus and
immediately available to furnish
assistance and direction throughout the
performance of the procedure.ÆÆ
We appreciate your review and consideration of this recommendation.
Tricia L. Sommer
7. Attachment: