

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
CERTIFICATE OF NEED (CON) SPECIAL COMMISSION MEETING**

Thursday, January 24, 2008

Capitol View Building  
201 Townsend Street  
MDCH Conference Center  
Lansing, Michigan 48913

**FINAL MINUTES**

**I. Call To Order**

Chairperson Hagenow called the meeting to order at 9:34 a.m.

A. Members Present:

Norma Hagenow, Chairperson  
Bradley N. Cory  
Dorothy E. Deremo  
Marc Keshishian, MD  
Adam Miller  
Michael A. Sandler, MD  
Thomas M. Smith  
Michael W. Young, DO (Arrived @ 9:38 a.m.)

B. Members Absent:

Edward B. Goldman, Vice-Chairperson  
Peter Ajluni, DO  
Kathie VanderPloeg-Hoekstra

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath  
Sally Flanders  
William Hart  
John Hubinger  
Joette Laseur  
Irma Lopez  
Nick Lyon  
Andrea Moore  
Taleitha Pytlowanyj  
Brenda Rogers

## **II. Review of Agenda**

Motion by Commissioner Cory, seconded by Commissioner Keshishian, to accept the agenda as presented. Motion Carried.

## **III. Declaration of Conflicts of Interest**

No conflicts were stated at this time.

## **IV. Review of Minutes – December 11, 2007**

Motion by Commissioner Deremo, seconded by Commissioner Young, to approve the minutes as presented. Motion Carried.

## **V. Hospital Beds – October 31, 2007 Public Hearing Summary & Report**

### **A. Public Comment**

Dennis McCafferty, Economic Alliance for Michigan  
Monica Harrison, Oakwood Healthcare (Attachment A)

### **B. Commission Discussion**

Ms. Rogers provided a brief overview of the Hospital Bed report (Attachment B). Commissioner Sandler wanted to clarify that the Hospital Bed Standards will not be up for review again until 2011. Further, he requested clarification regarding updating data. Ms. Rogers stated that the Department will update the data for 2008 and then again in 2010. Commissioner Deremo stated that she has a conflict of interest because she sits on the Oakwood Board and Oakwood Health Systems has submitted testimony regarding Hospital Beds. Commissioner Sandler stated he felt there should not be a Standard Advisory Committee (SAC) appointed. Discussion followed.

### **C. Commission Action**

Motion by Commissioner Smith, seconded by Commissioner Miller, to accept the Department's recommendations of having the Department re-calculate the bed need numbers, allow the Department to make technical changes, which both will be included in the final recommendation to the Commission, no change to the CON standards review cycle, and to not appoint a SAC. Motion Carried, 7-approve and Commissioner Deremo abstained.

## **VI. Megavoltage Radiation Therapy (MRT) Services – October 31, 2007 Public Hearing Summary & Report**

### **A. Public Comment**

E. James Potchen, MD, Michigan State University  
Melissa Cupp, Wiener Associates on behalf of Karmanos  
Bob Meeker, Spectrum Health  
Dennis McCafferty, Economic Alliance for Michigan

### **B. Commission Discussion**

Ms. Rogers provided a brief overview of the MRT Services report (Attachment C). Ms. Rogers clarified that the Department would be able to provide information to the

Commission at the March 11, 2008 meeting regarding Proton Accelerators. Commissioner Sandler stated he has concern regarding radiation oncologists and rural facilities. Commissioner Keshishian stated that he felt the Commission should appoint a Workgroup. Chairperson Hagenow stated that she would like Commissioner Keshishian to be the Commission Liaison for the Workgroup. Discussion followed.

C. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to accept the Department's recommendations to continue regulating MRT services/units, and do a broader review of the requirement for on site radiation oncologist during operation of the unit in a rural facility, review the definition to replace an existing MRT unit, review the criteria for expansion with a special purpose MRT unit, review Equivalent Treatment Visit (ETV) weight for IGRT, review proton therapy with collaboration as a requirement, and appoint a Workgroup to discuss the main issues noted by the Department. Motion Carried, 8-0.

The Workgroup will report to the Commission at its March 11<sup>th</sup> meeting on the proton therapy issue. All other issues, if not completed, can be reported to the Commission at its June 11<sup>th</sup> meeting.

**VII. Positron Emission Tomography (PET) Scanner Services – October 31, 2007 Public Hearing Summary & Report**

A. Public Comment

Dennis McCafferty, Economic Alliance for Michigan

B. Commission Discussion

Ms. Rogers provided a brief overview of the PET Scanner Services report (Attachment D).

C. Commission Action

Motion by Commissioner Keshishian, seconded by Commissioner Smith, to have the Department continue to research emerging technology, to have the data ready for discussion the next time that they are up for review, and to continue regulation of the PET Scanner Services. Motion Carried, 8-0.

**VIII. Surgical Services – October 31, 2007 Public Hearing Summary & Report**

A. Public Comment

Dennis McCafferty, Economic Alliance for Michigan

B. Commission Discussion

Ms. Rogers provided a brief overview of the Surgical Services report (Attachment E).

C. Commission Action

Motion by Commissioner Cory, seconded by Commissioner Young, to accept the Department's recommendations of continuing regulation of Surgical Services, continue volume requirements for all operating rooms, draft changes to clarify the language

regarding Documentation of Projections and to make necessary technical changes to be ready to present to the Commission at the March 11, 2008 meeting. Motion Carried, 7-0.

**IX. Cardiac Catheterization (CC) Services – October 31, 2007 Public Hearing Summary & Report**

A. Public Comment

Dennis McCafferty, Economic Alliance for Michigan  
Dan Witt, Metro Health

B. Commission Discussion

Ms. Rogers provided a brief overview of the CC Services report (Attachment F). Commissioner Deremo asked if the Department would look at Mr. Witt's concern regarding radio frequency ablation. Discussion followed.

C. Commission Action

Motion by Commissioner Deremo, seconded by Commissioner Cory, to accept the Department's recommendations to continue regulation of CC Services, to review the CC standards again in 2011, and to have the Department gather data regarding radio frequency ablations. Motion Carried, 8-0.

**X. Open Heart Surgery (OHS) Services – October 31, 2007 Public Hearing Summary & Report**

A. Public Comment

Dennis McCafferty, Economic Alliance for Michigan

B. Commission Discussion

Ms. Rogers provided a brief overview of the OHS Services report (Attachment G).

C. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the Department's recommendations to continue regulation of OHS Services and to review the OHS standards during their next review cycle in 2011. Motion Carried, 8-0.

**XI. Public Comment**

Steven Szelag, University of Michigan  
Robert Meeker, Spectrum Health  
Dennis McCafferty, Economic Alliance for Michigan

**XII. Review of Commission Work Plan**

A. Commission Discussion

Ms. Rogers provided a brief overview of the Work Plan (Attachment H). Commissioner Deremo questioned if the Department was going to focus on compliance more. Discussion followed.

Public Comment

Patrick O'Donovan, William Beaumont

B. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Young, to approve the Work Plan. Motion Carried, 8-0.

**XIII. Future Meeting Dates**

March 11, 2008

June 11, 2008

September 16, 2008

December 9, 2008

**XIV. Adjournment**

Motion by Commissioner Keshishian, seconded by Commissioner Miller, to adjourn the meeting at 11:40 a.m. Motion Carried, 8-0.

**Public Testimony Regarding Hospital Bed Standards  
Presented at Special Commission Meeting – January 24, 2008  
By: Oakwood Healthcare, Inc.**

Oakwood Healthcare, Inc., located in Dearborn, Michigan, operates four licensed hospitals with 1,307 inpatient hospital beds in west and southwest Wayne County and offers an array of hospital outpatient, diagnostic, physician, and other medical services, including inpatient psychiatric services.

Oakwood remains concerned as to current CON policies for replacement of existing licensed hospital beds to new physical plant and the scope of the current hospital replacement zone. Many valid concerns about this issue were raised but not resolved during the Hospital Bed SAC and Work Groups that were convened in 2006 and early 2007. We do not believe that the current Standards are consistent with the CON statutory goals of addressing cost, quality and access specifically as it relates to aging physical plant/hospital buildings. In the long term, maintenance of old buildings will be more costly to the health care system and make it more difficult for older hospital facilities to continue to deliver quality health care. The CON regulatory process should not include disincentives to quality improvements to the healthcare system in Michigan. The continued aging of hospitals in this State will challenge such hospitals to cope with projected health professional staffing shortages in upcoming years as many existing facilities are outmoded, inefficient, and in many instances, may require more staff than a new hospital facility with a modern efficient design and labor saving technologies.

Currently, of the four hospitals operated by Oakwood, three hospitals are located in

buildings that are 45 years in age or older. Although Oakwood continues to maintain and improve these facilities, we anticipate that at some point in the reasonably near future, it may be more cost-effective for Oakwood to simply replace one or more of its existing hospitals to new physical plant. With respect to Oakwood's service area, there are potential barriers to situating new hospital facilities within the current two-mile replacement zone.

The Commission, the Department, providers, payors and the citizens of the State of Michigan would be well served by further consideration of these issues.

Thank you for the opportunity to provide these comments.

**Michigan Department of Community Health (MDCH) Comments and Recommendations  
for Certificate of Need (CON) Review Standards  
Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

<b>HOSPITAL BEDS</b>			
(Please refer to MDCH staff summary of comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of Hospital Beds under CON.	N/A		Hospital Beds are not a covered clinical service. Therefore, de-regulation of Hospital Beds is not up for consideration.
2. Review comparative review criteria because 45% of the possible points in a comparative review are determined by payor mix.	No	None at this time	Thoroughly discussed with the last revisions (effective 3/8/07).
3. Replacement of existing licensed hospital beds to new physical plant space and the scope of the current hospital replacement zone.	No	None at this time	MDCH has completed review of information and comments submitted subsequent to the 2007 activity on this topic. There is no new or emerging information of a compelling nature that would necessitate additional action during this review cycle.
4. Modifications to allow for freestanding long-term (acute) care hospitals (LTACHs) that would operate as separate and distinct facilities outside the physical plant of an existing hospital.	No	None at this time	This issue should be addressed in conjunction with the next scheduled review of hospital bed standards.
5. CON standards review cycle and data suggestions for all CON review standards.	No	None at this time	Take the data suggestions under advisement with the review of each standard.
6. Make technical changes and updates that provide uniformity in all CON	Yes	Draft language, which includes re-calculation of the bed need	The Department will re-calculate the bed need numbers as



**Michigan Department of Community Health (MDCH) Comments and Recommendations  
for Certificate of Need (CON) Review Standards  
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standards; i.e. Medicaid, revisions to reference of on-line system; make additional technical changes under Sections 2 and 6; re-calculate bed need numbers		numbers, will be developed by MDCH staff	soon as the 2006 MIDB data is obtained.
<b>Recommendation: The Department recommends that the Commission assign responsibility to Department staff to draft technical changes and re-calculate the bed need numbers (#6) for appropriate Commission review and public comment.</b>			

## HOSPITAL BEDS

### Summary of 10/31/07 Public Hearing Comments and Department Comments – Working Document

Prepared by: MDCH

Considerations from 10/31/07 Public Hearing.	
<p><b>Public Hearing Summary.</b> The complete oral and written testimonies are included in the January 24, 2008 CON Commission meeting binders. The agencies represented were as follows:</p> <ul style="list-style-type: none"> <li>• Spectrum Health (Written): The current standards are reasonable and have served the state well - no major changes need to be made.</li> <li>• William Beaumont Hospital (Written): Comparative review criteria should be reviewed by the Commission because 45% of the possible points in a comparative review are determined by payor mix.</li> <li>• Oakwood Healthcare, Inc. (Written): Replacement of existing licensed hospital beds to new physical plant space and the scope of the current hospital replacement zone need to be reviewed.</li> <li>• Northern Michigan Regional Hospital (Written): Modifications to allow for freestanding long-term (acute) care hospitals that would operate as separate and distinct facilities outside the physical plant of an existing hospital.</li> <li>• Economic Alliance for Michigan (Verbal and Written): 1) Recommends that the next review be scheduled for 2009, not 2010, with no review in 2008. 2) All CON review standards that rely upon data should automatically use the most currently available data from either the MIDB or the MDCH Annual Surveys with annual updates of the data being done no later than 60 to 90 days following receipt of the data. 3) Every CON review standard that requires a projection of minimum volumes to justify a new program should be based on actual, historical referral data and not based upon the unverifiable projections of future referrals. 4) Organizations/providers seeking to start a new CON-approved program should not use any data to support their application that would result in a current CON-approved program falling below the CON minimum volume for that service.</li> </ul> <p>MDCH: 1) Add language under Section 1, Applicability, for Medicaid (technical change being made throughout the CON review standards). 2) Re-calculate bed need numbers. 3) Other technical changes.</p>	<p><b>Policy Issues to be Addressed</b></p> <p>Recognizing the aging of the hospitals in Michigan, the Department could recommend taking another look at replacement of existing licensed hospital beds to new physical plant space and the scope of the current hospital replacement zone. This could be done by the Department with a workgroup or with Standard Advisory Committee (SAC). Modifications to allow for freestanding long-term (acute) care hospitals that would operate as separate and distinct facilities outside the physical plant of an existing hospital needs further review. Again, this could be done by the Department with a workgroup or with a SAC. The technical changes, including re-calculation of the bed need numbers, would be drafted by the Department and would be included in the final recommendation to the Commission.</p> <p>If the Commission chooses to only address the technical changes and re-calculation of the bed need numbers, the Department would draft the language for proposed action for the Commission's September 16, 2008 meeting.</p> <p>The Department recommends no change to the CON standards review cycle. Maintaining a set schedule for the review of CON standards is administratively feasible. As far as the proposed recommendations regarding the data (for all standards), the Department suggests taking this under advisement with the review of each standard. Therefore, no change recommended, unless applicable to a standard under current review.</p> <p>A more detailed analysis is included on the following pages.</p>

1. Review comparative review criteria because 45% of the possible points in a comparative review are determined by payor mix. Note: Consideration from 10/31/08 Public Hearing.

**Current Standards**

Sec. 13(3)(a) and (b) (Applicants not in Limited Access Areas):

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume and as measured by percentage of gross hospital revenues as set forth in the following table. The applicant's uncompensated care volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the Department for purposes of calculating disproportionate share hospital payments.

Percentile Ranking Points Awarded

90.0 – 100 25 pts

80.0 – 89.9 20 pts

70.0 – 79.9 15 pts

60.0 – 69.9 10 pts

50.0 – 59.9 5 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the health service area percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the department for purposes of calculating disproportionate share hospital payments.

percentile rank points awarded

87.5 – 100 20 pts

75.0 – 87.4 15 pts

62.5 – 74.9 10 pts

50.0 – 61.9 5 pts

less than 50.0 0 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

**Policy Perspective**

This was thoroughly discussed with the last revisions (effective 3/8/07), and the statutory requirement, MCL 333.22230, mandates "In evaluating applications for a health facility as defined under section 22205(1)(c) in a comparative review, the department shall include participation in title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396r-6 and 1396r-8 to 1396v, as a distinct criterion, weighted as very important, and determine the degree to which an application meets this criterion based on the extent of participation in the medicaid program."

No change is recommended at this time.

Sec. 14(3)(a) and (b) (Applicants in Limited Access Areas):  
 (3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Ranking Points Awarded

- 90.0 – 100 25 pts
- 80.0 – 89.9 20 pts
- 70.0 – 79.9 15 pts
- 60.0 – 69.9 10 pts
- 50.0 – 59.9 5 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the statewide percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Rank Points Awarded

- 87.5 – 100 20 pts
- 75.0 – 87.4 15 pts
- 62.5 – 74.9 10 pts
- 50.0 – 61.9 5 pts
- Less than 50.0 0 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

2. Replacement of existing licensed hospital beds to new physical plant space and the scope of the current hospital replacement zone. Note: Consideration from 10/31/07 Public Hearing.

**Current Standards**  
 Sec. 2(1):  
 (dd) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for

**Policy Perspective**  
 The current CON review for standards for hospital beds allow for replacement of facilities. The issue identified in testimony is the same that has been reviewed several times in the past – limitations of the size of the replacement zone.

relocation in a different subarea as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(ee) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital subarea as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(ll) "Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital subarea or HSA. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(nn) "Replacement beds in a hospital" means hospital beds that meet all of the following conditions; (i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently licensed; (ii) the hospital beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.); and (iii) the hospital beds to be replaced will be located in the replacement zone.

(oo) "Replacement zone" means a proposed licensed site that is (i) in the same subarea as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

### **Section 7. Requirements for approval -- replacement beds in a hospital in a replacement zone**

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing replacement beds in a hospital in the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

Since 2004, two SACs and a Department workgroup have reviewed this issue. The latest report was presented to the Commission in March 2007. At that time, the following determinations were made:

- "While there is considerable information that "green" technology can provide cost savings, this information does not by itself lead to the conclusion that there is a need to rebuild hospitals outside of the replacement zone.
- Hospitals are generally available statewide and access greater than 30 minutes travel time does not appear to be a problem for the state.
- A combination of the other data available to the department at this time requires the conclusion that a change in standards is not necessary.
- The Department has not yet however, received detailed information supporting the specific proposals for individual hospitals who wish to move.

In summary, the Department has completed its review of the currently available information. As is always the case with CON, further future review in response to new or emerging information of a compelling nature may be necessary during the next regular statutory review of the hospital beds need methodology."

In 2005, Michigan's beds per 1,000 population was 2.6 (this has remained constant since 2000), while the national average per 1,000 population was 2.7 (this has slowly declined since 2000)\*. This would lead one to believe that the actual number of beds in Michigan is consistent with the nation. However, since Michigan's hospitals are continuing to age, and no specific recommendations have been identified for replacement within the current replacement zone if there are barriers, i.e., landlocked, some alternatives that could be explored, in addition to what has been previously looked at, include:

- Consideration of language that would allow for replacement outside the replacement zone, but still within the same subarea as long as there is a bed need for that subarea (similar to the Nursing Home and Hospital Long-term Care).
- Have MSU Geography Department (or other entity) look at other alternatives to identify need and/or placement of hospitals within the State of Michigan.

Further review of the issue could be considered.

<p>(2) In order to be approved, the applicant shall propose to (i) replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (ii) that the proposed new licensed site is in the replacement zone.</p> <p>(3) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.</p>	<p>*Source: National Directory State Certificate of Need Programs Health Planning Agencies 2007</p>
<p>3. Modifications to allow for freestanding long-term (acute) care hospitals (LTACHs) that would operate as separate and distinct facilities outside the physical plant of an existing hospital. Note: Consideration from 10/31/07 Public Hearing.</p>	
<p><b>Current Standards</b></p> <p>Sec. 6(2):</p> <p>(2) An applicant proposing to begin operation as a new long-term (acute) care hospital or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:</p> <p>(a) If the long-term (acute) care hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as a long-term (acute) care hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as a long-term (acute) care hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.</p> <p>(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least <u>all</u> of the following:</p> <p>(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital.</p> <p>(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.</p> <p>(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part application to replace the fixed units is submitted to the Department.</p> <p>(vi) The proposed mobile UESWL unit is projected to perform at least of the new hospital must be disposed of by one of the following means:</p> <p>(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the long-term (acute) care hospital. In the event that</p>	<p><b>Policy Perspective</b></p> <p>The current standards allow for freestanding LTACHs provided that there is a bed need in the subarea. Further, the existing language only allows for the use of existing beds from a hospital to set up a LTACH within that host hospital. The question is should you be able to use existing beds from a hospital(s) to set up a freestanding LTACH (the physical relocation of beds from a licensed site to another geographic location).</p> <p>The physical relocation of beds from a licensed site to another geographic location could also be tied to the replacement issue if it is allowed.</p> <p>Needs further review.</p>

the host hospital applies for a CON to acquire the long-term (acute) care hospital [including the beds leased by the host hospital to the long-term (acute) care hospital] within six months following the termination of the lease with the long-term (acute) care hospital, it shall not be required to be in compliance with the hospital bed supply set forth in Appendix C if the host hospital proposes to add the beds of the long-term (acute) care hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

- (B) Delicensure of the hospital beds; or
- (C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

- (d) The new licensed hospital shall remain within the host hospital.
- (e) The new hospital shall be assigned to the same subarea as the host hospital.
- (f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(3) of these standards.
- (g) The lease will not result in an increase in the number of licensed hospital beds in the subarea.
- (h) Applications proposing a new hospital under this subsection shall not be subject to comparative review.

4. CON standards review cycle and data suggestions for all CON review standards. Note: Consideration from 10/31/07 Public Hearing.

**Current Standards**

Sections vary under each set of CON review standards.

**Policy Perspective**

Maintaining a set schedule for the review of CON standards is administratively feasible, and it allows for a more consistent review of the standards. No change recommended.

As far as the proposed recommendations regarding the data (for all standards), the Department suggests taking this under advisement with the review of each standard. Each set of CON review standards has applicable sections that would have to be reviewed and potentially modified. Each set of standards would still need to go through the formal process of proposed

	<p>action, public hearing, and final action.</p> <p>Therefore, no change recommended, unless applicable to a standard under current review.</p>
<p>5. Other technical changes. Note: Consideration from MDCH.</p>	
<p><b>Current Standards</b></p> <p>Add new subsection under Section 1 for Medicaid applicability.</p> <p><b>Section 2(1)(a), (t), &amp; (u)</b></p> <p>(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a hospital with a valid license and which does not involve a change in bed capacity.</p> <p>(t) "Host hospital," for purposes of these standards, means an existing licensed hospital, which delicenss hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a long-term (acute) care hospital, or alcohol and substance abuse hospital, to begin operation.</p> <p>(u) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.</p> <p><b>Section 6(2)(b) &amp; (b)(i)</b></p> <p>(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least <u>all</u> of the following:</p> <p>(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital.</p> <p><b>Section 17. Requirements for approval – all applicants</b></p> <p>Sec. 17. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is a new provider not currently enrolled in Medicaid shall provide a signed affidavit stating that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.</p> <p>Section 9(2):</p> <p>(2) The agreements and assurances required by this section shall be in</p>	<p><b>Policy Perspective</b></p> <p>Technical changes being made throughout the CON review standards to accommodate the CON application on-line system and for consistency throughout the standards as applicable. Additional technical changes for clarity under sections 2 and 6 as follows (consistent with Department practice and policy):</p> <p><b>Section 2(1)(a), (t), &amp; (u)</b></p> <p>(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a <u>hospital with a valid license AND OPERATING HOSPITAL</u> and which does not involve a change in bed capacity.</p> <p>(t) "Host hospital," for purposes of these standards, means <u>an existing</u> licensed <u>AND OPERATING</u> hospital, which delicenss hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a long-term (acute) care hospital, or alcohol and substance abuse hospital, to begin operation.</p> <p>(u) "Licensed site" means <u>either (i) in the case of a single site hospital,</u> the location of the facility authorized by license and listed on that licensee's certificate of licensure <u>or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.</u></p> <p><b>Section 6(2)(b) &amp; (b)(i)</b></p> <p>(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement <u>AND RENEWAL OF A LEASE</u> between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least <u>all</u> of the following:</p> <p>(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital <u>OR ANY SUBSEQUENT APPLICATION TO ADD ADDITIONAL BEDS.</u></p> <p>The Commission needs to ask the Department to re-calculate the acute care bed need methodology to be completed by September 2008. The Department suggests the base year as 2006 and the planning year as 2011. The last re-</p>



the form of a certification authorized by the governing body of the applicant or its authorized agent.

**Section 5. Bed Need**

Sec. 5. (1) The bed-need numbers incorporated as part of these standards as Appendix C shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Commission shall direct the Department, effective November 2004 and every two years thereafter, to re-calculate the acute care bed need methodology in Section 4, within a specified time frame.

(3) The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).

(4) When the Department is directed by the Commission to apply the methodology pursuant to subsection (2), the effective date of the bed-need numbers shall be established by the Commission.

(5) As directed by the Commission, new bed-need numbers established by subsections (2) and (3) shall supersede the bed-need numbers shown in Appendix C and shall be included as an amended appendix to these standards.

Section 2(1):

(c) "Base year" means the most recent year that final MIDB data is available to the Department unless a different year is determined to be more appropriate by the Commission.

(ii) "Planning year" means five years beyond the base year, established by the CON Commission, for which hospital bed need is developed, unless a different year is determined to be more appropriate by the Commission.

run (effective September 19, 2006) used 2005 as the base year and 2010 as the planning year. Note: the Department will not be able to re-calculate until we receive the 2006 MIDB data.

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

<b>MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS</b> (Please refer to 1.14.08 MDCH staff analysis for additional detail – attached)			
<b>All Identified Issues</b>	<b>Issues Recommended as Requiring Review</b>	<b>Recommended Course of Action to Review Issues</b>	<b>Other/Comments</b>
1. Continued regulation of MRT services/units under CON	Yes	MRT standards to be reviewed in 2008, according to its scheduled three year cycle in the CON review process	CON regulation of MRT services/units appears to be working in Michigan and has broad support.
2. Review requirement of on site radiation oncologist during operation of the unit in a rural facility	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	Two modifications were suggested
3. Review definition to replace an existing MRT unit	Not applicable	MDCH research indicates that the suggested language modification cannot be applicable for all MRT units	
4. Review criteria for expansion with a special purpose MRT unit	No	MDCH supports the current expansion criteria in the MRT standards for a special purpose MRT unit	
5. Review Equivalent Treatment Visit (ETV) weight for IGRT	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	One modification has been suggested
6. Review nuclear particle accelerator technology (proton therapy)	Yes	MDCH can gather expert opinion and present a recommendation to the Commission	Suggestion to gain insight into this alternative treatment option and its future proliferation
7. Review criteria for modification of the Appendices	No	MDCH advisory posted on CON web site addresses the issue	Updated Appendices were presented to the Commission at the December 2007 meeting and given immediate effect

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
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8. Technical changes in language to be uniform with other CON standards	Yes	Review draft language developed by MDCH staff	
<b>Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft technical changes (#8) for appropriate Commission review and public comment. Additionally, the Department recommends that the Commission request the Department to obtain expert opinion as appropriate, and bring back recommendations for items 2, 5 and 6 at the June 11, 2008 meeting.</b>			

Michigan Department of Community Health  
**MEMORANDUM**  
 Lansing, MI

DATE: January 14, 2008

TO: Irma Lopez

FROM: Umbrin Ateequi

RE: Summary of Public Hearing Comments on Megavoltage Radiation Therapy (MRT) Standards and MDCH Policy Staff Analysis

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**Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Megavoltage Radiation Therapy (MRT) standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. The information below is a summary of the testimonies received. The complete oral and written testimonies are included in the January 24, 2008 CON Commission meeting binders. The facilities/organizations represented were as follows:

Oral Testimony Summary

None

Written Testimony Summary

Five individuals provided written testimony, representing five facilities/organizations.

1. *Nelson L. Adamson, MD, Dickinson County Healthcare System:*  
 Represent the only radiation oncologist on the medical staff in a rural facility, overseeing the radiation oncology service that is a joint venture between Dickinson County and Marquette General Health Systems. The current CON standards, Section 15(B)(iv), state that “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during operation of the unit(s).” Propose that the wording of this passage be modified to state that “All MRT treatments shall be performed under the supervision of a radiation oncologist. At least one physician will be on site at the geographic location of the unit during the operation of the unit(s).” Believe this minor change would benefit patients and practitioners, while maintaining sufficiently high level of care. This would allow small rural solo practices to maintain adequate staffing, while allowing the radiation oncologist to pursue state, federal, and specialty board mandated requirements for recertification and continuing medical education. Flexibility in scheduling would also allow small rural based practices to accommodate patients that travel great distances for daily radiation treatments,

with less fear of job loss or disruption for patients. Finally, this scheduling flexibility would also allow patients (especially the frail elderly) who have to travel great distances to be seen for follow-up, to be examined at a clinic closer to home, if the radiation oncologist is permitted to make these occasional visits to the community clinic. Since this could potentially lead to abuse, a reasonable approach to ensure that the radiation oncologist is available for patients under his/her care should include some wording that stipulates a minimum requirement. Being present for 80% of the treatment sessions seems reasonable. This would mean being in the clinic 4 out of 5 days.

2. *Kenneth Chu, Ph.D., A.B.R., P.Eng., Chief Medical Physicist, Marquette General Hospital:*

The current CON standards, Section 15(B)(iv), state that “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during operation of the unit(s).” Propose an additional clause that states, “In cases where there is only a solo radiation oncologist (in rural or micropolitan statistical areas) who does not service any other clinics, a radiation oncologist shall be on-site 90% of the hours when patients are being treated. At least one physician shall be on-site in or immediately available to the MRT unit at all times when patients are being treated.” Understand that the current standard prevents abuse by certain radiation oncologist practices where there may be one radiation oncologist servicing several clinics, and not being available to all the patients most of the time. However, in a solo practice (in rural areas), the current standards do not allow for the radiation oncologist to be ill, late, visit other hospitals for inpatient consults, or attend meetings, except outside of treatment hours.

3. *Robert Meeker, Spectrum Health:*

Support maintaining the MRT standards in their current form, with only minor modifications:

- The current standards include a definition of “Replace/upgrade an existing MRT unit” which is ambiguous. Recommend that this be revised to simply define “Replace an existing MRT unit” as follows: “Replace an existing MRT unit means an equipment change of an existing MRT unit, that requires a change in the radiation safety certificate, proposed by an applicant which results in that applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the project completion, at the same geographic location.” This resembles the language defining replacement of a CT scanner, as recommended by the CTSAC.
- The existing requirements for adding a special purpose MRT unit to an existing MRT service specify that the special purpose unit must be placed at the same location as the existing MRT units. With the physical expansion of large medical centers, this requirement may be too restrictive. Recommend that the location requirement for adding a special purpose MRT be broadened slightly to parallel the CMS definition of

“campus”, currently defined as within 250 yards of the main hospital building(s).

- With the advent of a new procedure technology, Image Guided Radiation Therapy (IGRT), recommend that it be added to the list of treatments and given an Equivalent Treatment Visit (ETV) weight of 2.5, which is the same as for IMRT.
- In regards to Section 3 of the MRT standards (Modification of the Appendices), recommend that the language be strengthened so that, rather than modification of the data in Appendix A and B requiring Commission action to be updated, such modifications should be required to be performed automatically when more current data becomes available.

4. *Patrick O’Donovan, William Beaumont Hospital:*  
Support the continued regulation of MRT services and do not have any recommended changes for 2008.
5. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*  
Look forward to participating in a deliberative and open discussion on any potential changes proposed to these standards consistent with the statutory language requiring the Commission to review and, if necessary, revise each set of CON review standards at least every three (3) years. Wholeheartedly support the review of CON standards on the required three year schedule; not as some have suggested, three years from the last time the standard was modified.

### **Policy Issues to be addressed**

#### Continued regulation of MRT services/units under CON

Based upon the testimonies provided, as well as the goals being promoted by MDCH, the Department supports continued regulation of Megavoltage Radiation Therapy (MRT) Services/Units under CON.

In accordance to the various testimonies received, the Department recommends pursuing minor modifications to the MRT standards.

#### Requirement of on site radiation oncologist during operation of the unit in a rural facility

Ensuring the delivery of quality health care is one of the main goals of CON regulation. Section 15(B)(iv) of the current MRT standards require that “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be on site at the geographic location of the unit during the operation of the unit(s).” This quality assurance requirement is consistent with criteria required by CON standards for MRT services in other states, such as West Virginia, which mandates that “MRT services will be provided under the direction of an on-site licensed physician who is board-eligible or board-certified by the American Board of Radiology in Radiation Oncology. These personnel must be on-site, when services are being provided.”

However, based on testimony received and the reasons provided, the Department acknowledges the difficulties of a radiation oncologist in a solo practice in a rural or micropolitan statistical area to be on site 100% of the hours when patients are being treated. It has been suggested that while it is desirable that a radiation oncologist be present at all times during treatment administrations, it is not necessary for the daily execution of treatment, and that a regular physician on site may suffice to supervise during certain treatment procedures, as long as that replacement is for a very minimal portion of the hours when patients are being treated. The Department recommends that expert input be considered for the appropriate minimum requirement for a radiation oncologist to be present on site during treatment sessions.

#### Definition to replace an existing MRT unit

The Department encourages uniformity across the CON standards when appropriate. The current MRT standards define “Replace/upgrade an existing MRT unit” as “an equipment change that results in an applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the equipment change.”

The Department took into consideration public comment regarding this issue, which suggested that the definition of replacement for MRT units be revised similar to the recently approved replacement definition of a CT scanner by the CON Commission. However, all MRT units do not require a radiation safety certificate. As such, making the “Replace” definition similar to CT will not work for MRT.

#### Criteria for expansion with a special purpose MRT unit

The current MRT standards states in Section 5(2)(a) that an applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate that “An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant’s non-special MRT units *at the location* where the special purpose unit is to be located.” In order to allow hospitals maximum flexibility, while permitting the use of patient friendly outpatient centers, the following revised language was suggested in public testimony for Section 5(2)(a) of the MRT standards: “An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant’s non-special MRT units *at the same location (or in an adjacent location qualifying as part of the main campus under CMS rules)* where the special purpose unit is to be located.”

The Department does not support this suggestion, as the CON is specific to the facility; if the MRT service is hospital based, then the special purpose unit should be hospital based. The Department supports a continuum of care and keeping the service as one. Special MRT services should be part of a larger general oncology service and not separated. That is also the rationale behind why the current MRT standards require the service to start with high volume non-special MRT units, prior to adding a special purpose unit.

#### Equivalent Treatment Visit (ETV) weight for IGRT

The Department recognizes that with the advent of new procedure technology, the list of treatments and the corresponding procedure weights should be updated on a regular basis.

Image Guided Radiation Therapy (IGRT) was in fact included, with a definition, in the MRT standards during its last review and approval in 2005. The 2005 MRT SAC was charged with reviewing and updating all of the ETVs. At that time, the SAC determined that IGRT would not be given a separate weight. It was mentioned that IGRT is defined by CMS coding, and that data should be collected for use in the review of the standards in three years. The Department recommends review of this issue and suggests presenting data and analysis gathered from the MDCH Annual Survey to the experts for their recommendation in confirming the appropriate weight for IGRT.

Research indicates that IGRT is complementary to IMRT. IMRT is used to improve the radiation delivery precision and IGRT is used to improve the radiation delivery accuracy. IGRT combines a new form of scanning technology, which allows planar or X-ray Volume Imaging, with IMRT. This enables physicians to adjust the radiation beam based on the position of the target tumor and critical organs, while the patient is in the treatment position. With IGRT, higher doses of radiation can be focused and delivered directly to tumors and cancer cells, maximizing effectiveness. IGRT allows the precise delivery of radiation to tumors in real time while allowing normal tissues to receive minimal radiation. This procedure sets the stage for allowing the radiation oncologist to safely increase the radiation dose to tumors while minimizing side effects. Clinical studies have indicated that higher doses of radiation significantly improve local tumor control.

#### Nuclear particle accelerator technology (proton therapy)

According to a recent New York Times article (December 26, 2007), medical centers are looking to turn nuclear particle accelerators into the latest weapons against cancer:

“The machines accelerate protons to nearly the speed of light and shoot them into tumors. Scientists say proton beams are more precise than the X-rays now typically used for radiation therapy, meaning fewer side effects from stray radiation and, possibly, a higher cure rate. But a 222-ton accelerator, and a building the size of a football field with walls up to 18-feet thick in which to house it, can cost more than \$100 million. Until 2000, the United States had only one hospital-based proton therapy center. Now there are five, with more than a dozen others announced. Still more are under consideration. Some experts say there is a vast need for more proton centers. But others contend that the arms race mentality has taken hold, as medical centers try to be first to take advantage of the prestige, and the profits, a proton site could provide...

On the horizon is therapy using beams of carbon ions, which are said to be even more powerful in killing tumors. Touro University says it will build a combined proton and carbon therapy center outside San Francisco, to open as early as 2011. The Mayo Clinic is also seriously considering one. Such centers will cost even more – as much as \$300 million.”

It is unclear at this time if this treatment option is covered by the definition of MRT; Radiation Safety is currently reviewing the issue. The Department recommends expert review of this technology as an alternative treatment option to radiation therapy and insight into the potential for its proliferation in Michigan. Currently, there are no hospital-based proton therapy centers in Michigan.



#### Criteria for modification of the Appendices

On September 4, 2007, an advisory was posted on the CON web site that states, in part, "...the Department will utilize the most current submitted, verifiable and complete data available from the Michigan Cancer Surveillance Program for initiation of MRT and PET services..." This makes the most recent data available to all applicants.

The Department most recently updated the Duplication Rates and Duplication Factors using Hospital and Registry Reporting Sources (Appendix A), and the Distribution of MRT Courses by Treatment Visit Category (Appendix B). These updated appendices of the MRT standards were presented at the December 11, 2007 CON Commission meeting and given immediate effect.

#### Technical Changes and Updates

The Department is systematically modifying all CON review standards to achieve uniformity and to accommodate the CON application on-line system.

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

<b>POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES</b>			
<b>All Identified Issues</b>	<b>Issues Recommended as Requiring Review</b>	<b>Recommended Course of Action to Review Issues</b>	<b>Other/Comments</b>
1. Continued regulation of PET Services under CON?	Yes	Next scheduled review to be done in 2011.	Radiation Service needs to be regulated. Please see the note below.
2. Consider the addition of PET MR as a modality that should be included in the PET scanner services definition, similar to the treatment of PET/CT.	Not at this time	MDCH gather data over the next year or two.	Emerging Technology Issue  (The average unit price of hybrid PET/MRI Scanner is \$3.5 million. There is no dedicated reimbursement for PET/MRI studies performed on a hybrid scanner. Despite clinical promise, fused PET/MRI technology will not become widely available for another four to seven years.) <sup>1</sup>
3. Consider current CON limit on the commitment of data for the lifetime of the PET scanner service instead of five (5) years from the start of operations of a service as stated in the current PET scanner CON standards.	No	None	PET Standards were last reviewed in 2006. It became effective in March 2007. The commitment of data was changed from 3 to 5 years at that time. We do not have sufficient data to make a recommendation in any change in the policy.

<sup>1</sup> Technology Assessment Compendium – 2007 Reference Guide to Emerging Clinical Innovations

4. Consider PET standards to specifically address Positron Emission Mammography (PEM). PEM is an organ specific, high resolution PET scanner that involves the injection radioactive isotope.	Not at this time	MDCH gather data over the next year or two.	Emerging Technology Issue  (Note: This item was discussed by the PETSAC in 2006 and since there was no reimbursement at the time for this type of scanning, it was decided not to pursue any further.)
<b>Recommendation: The Department recommends that the Commission ask the Department to continue to research emerging technology in this area and have the data ready for discussion when the standards are next reviewed. The next scheduled review is 2011.</b>			

Note: Positron Emission Tomography (PET) Standards scheduled for review in 2008 should continue to be regulated.

Positron emission tomography, also called PET imaging or a PET scan, is a diagnostic examination that involves the acquisition of physiologic images based on the detection of radiation from the emission of positrons. Positrons are tiny particles emitted from a radioactive substance administered to the patient. The subsequent images of the human body developed with this technique are used to evaluate a variety of diseases.

PET must be done by a radiologist who has specialized in nuclear medicine and has substantial experience with PET.

Radiation is a risk which needs to be balanced with the benefit. The benefit is that we can have a source of power, or we can do scientific research, or receive medical treatments. The risks are a small increase in cancer.

There is a need to continue monitoring new technology that emerges in the area of PET scans.

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
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<b>Surgical Services</b> (Please refer to the attached MDCH staff analysis for additional details.)			
<b>All Identified Issues</b>	<b>Issues Recommended as Requiring Review</b>	<b>Recommended Course of Action to Review Issues</b>	<b>Other/Comments</b>
1. Should the covered service continue to be regulated?	Not Applicable	Continued Regulation.	
2. Inclusion of an exception to the volume requirements for an FSOF with one operating room that is contiguous to a freestanding emergency room that receives ambulance traffic.	No	No action.	See MDCH staff analysis on page 3.
3. Inclusion of language to clarify the process of deducting previously committed projections.	Yes	Draft recommended changes.	Inclusion of language would provide clarification on the established process within the Standards.
4. Department recommended technical changes.	Yes	Draft recommended changes.	Technical changes to the Standards to ensure uniformity within all CON Standards.
<b>Recommendation: The Department recommends that the Commission assign the responsibility to draft the necessary changes for 3 and 4 to Department staff. The Department shall present the draft language to the Commission for proposed action at its March 11, 2008 meeting.</b>			

## **MDCH Staff Analysis of the Surgical Services Standards**

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 Workplan, the Surgical Services Standards are scheduled for review in calendar year 2008.

### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. Testimony was received from three organizations and is summarized as follows:

1. The Michigan Health Ministries of Ascension Health
  - Supports continued review of the standards on a three-year schedule.
2. Spectrum Health Hospitals
  - Supports current standards with no modifications.
3. William Beaumont Hospitals
  - Supports continued regulation of surgical services.
  - Recommends language to clarify the process of deducting previously committed projections.
  - Recommends an exception from the volume requirement for a Freestanding Outpatient Surgery Facility (FSOF) with one operating room that is contiguous to a freestanding emergency room.

### **Regulation of Covered Service**

Michigan is one of 22 states which regulate surgical services within CON. The Department received testimony from two organizations which support the continued regulation of surgical services. The Surgical Services Standards require that operating rooms are exceeding volume levels prior to the initiation of a new service or expansion of an existing service. Thus, the regulation of Surgical Services ensures appropriate utilization of each operating room to keep Michigan right-sized.

### **Documentation of Projections**

The Department received a request to include language which outlines the process for documenting projections under Section 11 of the Standards. This would offer additional clarification to the Standards on the established administrative practice. The change would be technical in nature and Section 11(1) would be modified to read as follows:

- Section 11(1) An applicant required to project volumes of service shall specify how the projections were developed and shall include only surgical cases performed in an OR.
- (a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.
  - (b) The Department shall subtract any previous projections, pursuant to subsection 2(d).

**Volume Exception**

The Department received a request to include an exception to the volume requirements for an FSOF with one operating room that is contiguous to a freestanding emergency room that receives ambulance traffic. Ambulances are dictated by Administrative Rule 325.22112, which states:

R 325.22112(1) An ambulance operation, both ground and rotary, shall transport an emergency patient only to an organized emergency department located in and operated by a hospital licensed under part 215 of the code or to a freestanding surgical outpatient facility licensed under part 208 of the code that operates a service for treating emergency patients 24 hours a day, 7 days a week and complies with medical control authority protocols.

Pursuant to MCL 333.22205, a hospital licensed under part 215 and an FSOF licensed under part 208 are both classified as a health facility. A freestanding emergency room is not a health facility, but by having an FSOF, the freestanding emergency room becomes a health facility. With appropriate protocols, it can receive ambulance traffic.

The Surgical Services Standards require an applicant applying for a FSOF to provide projections from physicians, who commit to perform their cases at this proposed facility for three years. The standard ensures that the operating room will be able to meet the volume requirements. The exception would provide a non-health facility the ability to become a health facility and side step the standard of using historical cases to initiate a new service.

**Technical Changes**

The Department is recommending that an exception to the requirements for relocation of an existing service with one or two operating rooms, which is located in a rural or micropolitan statistical area county. This exception would be identical to the exception found in Section 6(3) of the Standards. The inclusion of this exception would give uniformity for replacing and relocating an existing service within the Standards.

**MDCH Staff Recommendations:**

- Continued regulation of surgical services to ensure that there is not a proliferation of this service within Michigan.
- Continued volume requirement for all operating rooms.
- Draft changes to the Standards to include the clarifying language under Documentation of Projections and the technical changes for presentation to the Commission at the March 11, 2008 meeting.

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<b>CARDIAC CATHETERIZATION (CC) SERVICES</b>			
<b>All Identified Issues</b>	<b>Issues Recommended as Requiring Review</b>	<b>Recommended Course of Action to Review Issues</b>	<b>Other/Comments</b>
1. Continued regulation of CC Services under CON?	Yes	Next scheduled review to be done in 2011.	Please see the note below.
2. Neither the Heart Rhythm Society, nor the American College of Cardiology have policies in place prohibiting qualified electrophysiologists from performing catheter-based radiofrequency ablations at facilities without on-site cardiac surgery. Given this, recommends reconsideration of this policy.	No	None (This issue was reviewed in 2007)	Ablation remains in the Therapeutic category, thus must be done at facility that can do emergent open heart surgery in the event of a burn through to the esophagus or one of the great vessels in the chest. Although this risk is small, especially in a very well trained electrophysiologist, not all electrophysiologists are trained to perform ablation.
3. Recommends seeing amended language that allows for non-complex ablations to be performed at hospitals without open heart surgery.	No	None (This issue was reviewed in 2007)	The committee did not undertake a discussion to rate "non-complex" versus "complex" in the context of facility ability to perform an ablation procedure at a non-Open Heart surgery site. The weight scores were calculated based upon the time and resources required to perform the particular procedure because of changes in technology and not on how "safe" they were to perform

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			<p>at non-Open Heart facilities. At this point in time, the recommendation is to keep the standard as it is for ablation therapeutic procedure (with the exception of the weighting changes) until such time that the technology advances or that all electrophysiologists are trained to perform ablation procedures. An EP procedure is a diagnostic procedure that carries little risk to the patient. All electrophysiologists are trained to perform EP procedures. Placing a pacemaker or ICD, which should be based upon diagnostic EP is reasonable and carries minimal risk to the patient. This was thoroughly discussed and was felt to be safe to perform in the absence of an Open Heart Program because of the minimal likelihood of complications requiring Open Heart support.</p>
<p><b>Recommendation: The Department recommends that the Commission review the CC Standards in 2011 when they are again scheduled for review. The currently approved standards have yet to be implemented, and then must have an opportunity to be evaluated before any new revisions are made to the standards.</b></p>			



Note: Cardiac Catheterization (CC) Services Standards Scheduled for review in 2008 should continue to be regulated. These Standards were originally due for review in 2005. An issue paper on 'Cardiac Catheterization and Open Heart Surgeries Volume Requirements' was submitted to the Commission in June 2005 and a full review by the CCSAC was able to be completed in 2007. In January 2007, the CON Commission appointed the CC Standards Advisory Committee (CCSAC) to review the existing standards based upon the CON principles of cost, quality and access. The charge to the CCSAC also included the task of reviewing new and emerging technology related to the cardiac catheterization. The SAC extensively deliberated a number of issues and made recommendations to the CON Commission in December 2007. The CON Commission accepted the SAC recommendations and final language is currently being reviewed by the Joint Legislative Committee and the Governor for their approval.

**MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review  
Presented to CON Commission January 24, 2008**

<b>OPEN HEART SURGERY (OHS) SERVICES</b> (Please refer to 1.14.08 MDCH staff analysis for additional detail – attached)			
<b>All Identified Issues</b>	<b>Issues Recommended as Requiring Review</b>	<b>Recommended Course of Action to Review Issues</b>	<b>Other/Comments</b>
1. Continued regulation of OHS services under CON	Yes	Department recommends that the OHS standards be reviewed again in 2011, following implementation of the recently approved OHS standards.	CON regulation of OHS services appears to be working in Michigan and has broad support.
2. No additional modifications to the Commission approved OHS standards	No	None at this time	Thoroughly discussed by the OHS SAC in 2007, with the Commission taking Final Action at its December 11, 2007 meeting to move the SAC recommended language, with the Department's Proposed Amendments to the Methodology (S-3), forward for review by the JLC and the Governor.
<b>Recommendation: The Department recommends that the Commission review the OHS standards during the next review cycle scheduled in 2011. The currently approved standards have yet to be implemented, and then have the opportunity to be evaluated before any changes are made to the standards.</b>			

Michigan Department of Community Health  
**MEMORANDUM**  
Lansing, MI

DATE: January 14, 2008  
TO: Irma Lopez  
FROM: Umbrin Ateequi  
RE: Summary of Public Hearing Comments on Open Heart Surgery (OHS) Standards and MDCH Policy Staff Analysis

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**Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Open Heart Surgery (OHS) standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. The information below is a summary of the testimonies received. The complete oral and written testimonies are included in the January 24, 2008 CON Commission meeting binders. The facilities/organizations represented were as follows:

Oral Testimony Summary

None

Written Testimony Summary

Five individuals provided written testimony, representing five facilities/organizations.

1. *Robert Meeker, Spectrum Health:*  
Endorse the work of the recently completed Open Heart Surgery Standards Advisory Committee and recommend final adoption of the proposed CON Review Standards for OHS services, with the inclusion of the S-3 need methodology. Do not believe that any additional modifications are required to these standards at his time, and recommend that they not be reopened for substantial revision for three (3) years.
2. *Patrick O'Donovan, William Beaumont Hospital:*  
Support the continued regulation of Open Heart Surgery services. Would further like to commend the SAC for its recent work in revising the standards, specifically, its recommendation to maintain the current standard minimum of 300 adult open heart procedures. Further support the efforts of the MDCH staff and the Commission in revising the methodology used to project need. As a result of these recent proposed revisions, Beaumont does not feel it is necessary for the Commission to review the standards in 2008. Beaumont also urges the

Commission to continue pressing the Department to routinely and consistently enforce CON regulation, including volume requirements.

3. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*  
Look forward to participating in a deliberative and open discussion on any potential changes proposed to these standards consistent with the statutory language requiring the Commission to review and, if necessary, revise each set of CON review standards at least every three (3) years. Wholeheartedly support the review of CON standards on the required three year schedule; not as some have suggested, three years from the last time the standard was modified.
  
4. *Melissa Cup, Wiener Associates:*  
Comments pertain specifically to the CON Standards for Open Heart Surgery Services with Proposed Amendments (S-3). Suggest some modifications to the proposed language that the Department has added to allow them to update the utilization weights on an annual basis, without having to go through the CON Commission for permission to do so.  
(Department Note: The suggested modifications have been adopted in the Final OHS language approved by the Commission at its December 11, 2007 meeting.)
  
5. *Marsha Manning, EAM/General Motors:*  
Preface EAM remarks by reporting that General Motors, and colleagues at Chrysler and Ford, have found that strong CON programs in the U.S. have been effective in controlling costs and improving the quality of healthcare services for employees and retirees if they are strong and well-developed, both in concept and implementation. Have found that the Michigan CON standards are among the most effective CON programs in accomplishing this objective in the approximately ten states in which these companies have significant membership.

Agree that the Commission should comply with the CON statutory requirement that each CON standard be reviewed every three (3) years for possible revision. This should mean that standards are not considered for possible review until three (3) years after the last time they were reviewed, unless there is some compelling reason, such as new developments in medical practice or other factors affecting the service. Some of the standards posted for this hearing include several of the standards that have undergone reviews in 2006 (Hospital Beds) and in 2007 (Cardiac Catheterization and Open Heart Surgery). Accordingly, would recommend that the next possible review of the Hospital Beds standards, last modified in 2006, be rescheduled for possible review in 2009. The next review of the two cardiac standards should be rescheduled for possible review in 2010.

The following process changes should be approved by the Commission for all CON standards:

1. All CON standards that rely upon data should automatically use the most currently available data from either the MIDB or the MDCH Annual Surveys. The update of data should not require a request of

the Commission or the approval of a SAC. Annually updating the data and its impact upon the standards should be done no later than 60 to 90 days following receipt of the data.

2. Every CON standard that requires a projection of minimum volumes to justify a new program should be based on actual, historical data and not based upon the unverifiable projections of future referrals.
3. Organization/providers seeking to start a new CON approved program should not use any data to support their application that would result in a current CON approved program falling below the CON minimum volume for that service.

In addition to these comments regarding the 2008 work plan, would like to support the proposed changes in the CON standards for Cardiac Catheterization and Open Heart Surgery, including the modification to the formula for predicting the need for any additional open heart surgery programs.

### **Policy Issues to be addressed**

#### Continued regulation of OHS services under CON

Based upon the testimonies provided, as well as the goals being promoted by MDCH, the Department supports continued regulation of Open Heart Surgery (OHS) Services under CON.

#### CON Commission approved OHS standards

The OHS standards underwent a thorough review by a Standard Advisory Committee (SAC) in 2007. The SAC completed its work on July 11, 2007 and provided the Commission with draft language at the September 18, 2007 meeting, thoroughly addressing all of its assigned charges, except one. The 2007 OHS SAC had as one of its goals, to review the methodology (adopted over 20 years ago) and make the appropriate updates. As final analytic data were not available to the SAC upon its statutorily designated 6 month deadline, the SAC recommended that the Department generate the needed data to permit updating of the relevant utilization weights.

Refinements to the OHS methodology for projecting the need for additional OHS programs in Michigan (proposed by MDCH and identified as S-3) were developed pursuant to strong requests by the SAC, the public, and the Commission. In developing this model, the Department worked with a broad group of stakeholders and solicited extensive public comment/input. These refinements have made much progress in strengthening the open heart methodology and have gone a long way to improve the predictability of this process.

Following much work and analyses, the Department posted draft language for consideration at the October 31, 2007 Public Hearing. This language included Proposed Amendments that incorporate the revised methodology of S-3. As can be seen from the various testimonies received (as the OHS standards are scheduled for review again in

2008, according to the scheduled three (3) year review cycle), the Department has received overall strong support for these recommended refinements to the OHS methodology. In addition, as these revisions are complete and address all issues raised to date, the Department is in agreement with the public testimony that the CON standards for OHS do not need to be reopened for revision in 2008. The CON Commission just recently, at its December 11, 2007 meeting, accepted the OHS SAC recommendations with the proposed amendments which includes the S-3 language, and moved it forward to the Joint Legislative Committee and the Governor for the 45-day review period. The approved standards have yet to be implemented, and then evaluated before any new changes are made to the standards. The Department recommends that the Commission review the OHS standards in 2011.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

### CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	J	F	M*	A	M	J*	J	A	S*	O*	N	D*	J*	F	M*	A	M	J*	J	A	S*	O*	N	D*
Air Ambulance Services	PH		DR	•	•	•—	P		▲						F									
Cardiac Catheterization Services	■	■	■	■	■	■	■		—	P PH		▲ F	DR •	•	•DR									
Computed Tomography (CT) Scanner Services	PH		DR	S■	■	■	■	■	■	■	■	■—		P	▲ F									
Hospital Beds	•	•	•	•	•	•R				PH			DR	•	•	•	•	•—	•P PH	•	•▲ F			
Magnetic Resonance Imaging (MRI) Services	P	•	▲F—		P				▲F				•	•	•R									
Megavoltage Radiation Therapy (MRT) Services/Units**										PH		R	DR	•	•—	•P PH	•	•▲ F						
Nursing Home and Hospital Long-term Care Unit Beds**	PH		DR	S■	■	■	■	■	■	■	■	■—	•	P•	▲ F •									
Open Heart Surgery Services	■	■	■	■	■	■	■	•	•—	•P PH	•	•▲ F	DR											
Psychiatric Beds and Services	•	•	•R	•	•	•R	•	•	•—	P		▲ F												
Surgical Services										PH			DR	•	•—	•P PH	•	•▲ F						
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	PH		DR	•	•	•R	•	•	•—	P		▲ F												
New Medical Technology Standing Committee	•M	•M	•MR	•M	•M	•M R	•M	•M	•M R	•M	•M	•M R A	•M	•M	•MR	•M	•M	•M R	•M	•	•M R	•M	•M	•M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

**KEY**

<ul style="list-style-type: none"> <li>— - Receipt of proposed standards/documents, proposed Commission action</li> <li>* - Commission meeting</li> <li>■ - Staff work/Standard advisory committee meetings</li> <li>▲ - Consider Public/Legislative comment</li> <li>** - Current in-process standard advisory committee or Informal Workgroup</li> <li>• - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work</li> </ul>	<ul style="list-style-type: none"> <li>A - Commission Action</li> <li>C - Consider proposed action to delete service from list of covered clinical services requiring CON approval</li> <li>D - Discussion</li> <li>F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period</li> <li>M - Monitor service or new technology for changes</li> <li>P - Commission public hearing/Legislative comment period</li> <li>PH - Public Hearing for initial comments on review standards</li> <li>R - Receipt of report</li> <li>S - Solicit nominations for standard advisory committee or standing committee membership</li> </ul>
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Approved January 24, 2008

Updated January 25, 2008

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, [www.michigan.gov/con](http://www.michigan.gov/con).

**SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS\***

<b>Standards</b>	<b>Effective Date</b>	<b>Next Scheduled Update**</b>
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	June 4, 2004	2011
Computed Tomography (CT) Scanner Services	December 27, 2006	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 13, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds, Addendum for Special Population Groups, and Addendum for New Design Model Pilot Program	December 3, 2004	2010
Open Heart Surgery Services	June 4, 2004	2011
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	October 17, 2005	2009
Surgical Services	June 5, 2006	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 4, 2004	2010

\*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

\*\*A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.