MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISION MEETING

Tuesday, March 11, 2008

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

APPROVED MINUTES

I. Call To Order

Vice-Chairperson Goldman called the meeting to order at 9:14 a.m.

A. Members Present:

Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO (left @ 2:58 p.m.)
Dorothy E. Deremo
Marc Keshishian, MD
Michael A. Sandler, MD (left @ 3:00 p.m.)
Thomas M. Smith
Kathie VanderPloeg-Hoekstra
Michael W. Young, DO

B. Members Absent:

Norma Hagenow, Chairperson
Bradley N. Cory
Adam Miller

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Umbrin Ateequi
Tulika Bhattacharya
William Hart
Larry Horvath
John Hubinger
Joette Laseur
Irma Lopez
Nick Lyon
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Vice-Chairperson Goldman recommended switching items IX and VII on the agenda.

Commissioner Sandler requested that all testimony for the items that will be discussed in the morning be taken first and wait to hear the testimony regarding the afternoon items until that time.

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the agenda as amended. Motion Carried.

III. Declaration of Conflicts of Interest

Commissioner Sandler stated he has a conflict of interest regarding Megavoltage Radiation Therapy (MRT) Services/Units and will address the issue at the time of discussion.

Vice-Chairperson Goldman stated he too has a conflict of interest regarding MRT.

IV. Review of Minutes – January 24, 2008

Motion by Commissioner Ajluni, seconded by Commissioner Keshishian, to approve the minutes as presented. Motion Carried.

V. Public Comments for Action Items (i.e. VI & IX)

Computed Tomography (CT) Scanner Services

Senator Joe Schwarz, MD, MichBio
Stephen Rapundalo, MichBio
Matt Jordan, Xoran Technologies
Raj Wiener, Wiener & Associates
Caroline Ruddell, MI Dental Association
Oren Sagher, University of Michigan Health Systems
Steven Szelag, University of Michigan Health System (Attachment A)
Amy Barkholz, MHA
Dennis McCafferty, Economic Alliance for Michigan

Nursing Home & Hospital Long-Term Care Unit (NH-HLTCU) Beds

Ian Engle, Consumers and residents
Brian Kaser, representing Baraga County Memorial Hospital
Amy Barkholz, MHA
Pat Anderson, HCAM
Susan Steinke, Self
Sarah Slocum, State LTC Ombudsman

VI. CT Scanner Services – Public Hearing Comments

A. Commission Discussion

Ms. Rogers provided a brief overview of the Public Hearing comments (Attachment B). She stated that Section 1(5) of the language should be deleted. Discussion followed.

B. Commission Final Action

There was discussion and agreement to exempt “o-arms” from the CT standards as the FDA does not define these as CT scanners. The Department will draft language for possible action later in the meeting.

Motion by Commissioner Deremo, seconded by Commissioner Young, to approve the Standards (Attachment C) with the understanding that there may be an amendment regarding ”o-arms,” accept the deletion of Section 1(5), have a workgroup look at dental CTs and whether a different/abbreviated application process is appropriate, continue review of the mini-scanner issue including ENT, dental, etc., and move the standards forward to the Joint Legislative Committee (JLC) and Governor to begin the 45-day review period. Motion Carried, 8-0.

Break from 11:02 a.m. to 11:17 a.m.

VII. MRT Services/Units – Workgroup Report

A. Review of Proposed Language

Commissioner Keshishian provided a PowerPoint presentation regarding the MRT Proton Accelerator (Attachment D). Ms. Ateequi provided a brief overview of the proposed language (Attachment E). Discussion followed.

Lunch Break from 12:08 p.m. to 12:50 p.m.

Public Comment

Patrick O’Donovan, William Beaumont
Richard Katz, ProCure Treatment Centers
Frank Vicini, MD, William Beaumont
Kenneth Gall, Still River Systems
Benjamin Movsas, Henry Ford Health Systems (Attachment F)
Bob Meeker, Spectrum Health
Tewfik Bichay, MD, Trinity-Health
Sean Gehle, Michigan Health Ministries of Ascension Health
Dennis McCafferty, Economic Alliance for Michigan

B. Commission Discussion

Commissioner Sandler and Vice-Chairperson Goldman stated they have a conflict of interest and will not be voting.

C. Commission Proposed Action

Motion by Commissioner Keshishian, seconded by Commissioner Smith, to accept the MRT standards with the amendments of deleting Section 1(5), in Section 10(1)(B)(I) replacing the words “WHICH INCLUDES” with “AND,” request the Department to look at the language regarding other interested entities, adding rationale language, look at the level of collaboration, and move forward for public hearing. Motion Carried, 6-yes and 2-abstentions.

VIII. NH-HLTCU Beds – Public Hearing Comments

A. MDCH Report

Ms. Rogers provided a brief overview of the documents provided to the Commissioners which are the NH-HLTCU Beds Standards with Proposed Amendments (Workgroup),

Memorandum regarding NH Quality Measures Workgroup Report, and Memorandum regarding Review of Public Hearing Testimony on the Proposed NH-HLTCU Beds Standards and Recommended Modifications (Attachments G, H, and I). Ms. Moore gave a brief overview of the recommended amendments to the NH-HLTCU Beds Standards with Proposed Amendments (Workgroup) (Attachment G). Discussion followed.

B. Commission Final Action

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to accept the amended standards by the workgroup including the Department recommendations with an effective date of June 2, 2008 for the standards and the updated bed need numbers, and move it forward to the JLC and Governor to begin the 45-day review period. Motion Carried, 8-0.

Motion by Commissioner Deremo, seconded by Commissioner Ajluni, to amend the language in Section 7(1)(A) to exempt HLTCUs from the 50% limitation and move it forward for public hearing.. Motion Carried, 8-0.

IX. Election of Officers

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to modify the agenda by taking action on item XXI now. Motion Carried.

Motion by Commissioner Deremo, seconded by Commissioner Ajluni, to nominate and elect Commissioner Goldman as the Chairperson and Commissioner Hagenow as the Vice-Chairperson. Motion Carried.

X. Surgical Services

A. Review of Proposed Language

Ms. Moore provided a brief overview of the proposed language (Attachment J).

B. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the proposed language with amendments and move it forward for public hearing. Motion Carried, 8-0.

XI. CT Scanner Services Amendment

Motion by Commissioner Keshishian, seconded by Commissioner Young, to accept the following amended language to Section 2(i): "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, NON-DIAGNOSTIC INTRA-OPERATIVE GUIDANCE TOMOGRAPHIC UNITS, AND CT SIMULATORS USED SOLELY FOR TREATMENT PLANNING PURPOSES IN CONJUNCTION WITH AN MRT UNIT," and move it forward for public hearing. Motion Carried, 6-yes, 1-abstention.

XII. Magnetic Resonance Imaging (MRI) Services – Intra-operative MRI (iMRI)

A. MDCH Report

Ms. Rogers provided a brief overview of the Department's report (Attachment K).

Public Comment

Dennis McCafferty, Economic Alliance for Michigan
Bob Meeker, Spectrum Health
Oren Sagher, University of Michigan Health Systems

B. Commission Discussion

Commissioner Sandler recommended not waiting until 2009 to review the MRI Services Standards. He stated he would have a workgroup meeting before the next Commission meeting.

C. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to have a workgroup meeting and have a report for the Commissioners on iMRI at their next meeting. Motion Carried, 8-0.

XIII. Cardiac Catheterization (CC) Services

A. MDCH Report

Ms. Rogers provided a brief overview of the Department's report (Attachment L).

Public Comment

Dan Witt, Metro Health Hospital (Attachment M)
Bob Meeker, Spectrum Health
Dennis McCafferty, Economic Alliance for Michigan

B. Commission Action

Motion by Commissioner Keshishian, seconded by Commissioner Deremo, to accept the Department's report with no further review of the CC standards at this time. Motion Carried, 6-0.

XIV. Standing New Medical Technology Advisory Committee (NEWTAC) – Report

A. Vascular Surgery

1. Commission Discussion

Commissioner Keshishian provided a brief overview of his report (Attachment N).

2. Commission Action

Motion by Commissioner Keshishian, seconded by Commissioner Young, not to regulate vascular surgery, and have the Chair draft a letter to Senator George advising him of the Commission's decision. Motion Carried, 6-0.

B. Proposed Criteria/Guidelines for Determining Whether a Clinical Service Should be Covered Under CON

1. Commission Discussion

Commissioner Keshishian provided a brief overview of the proposed criteria/guidelines (Attachment O).

2. Commission Action

Motion by Commissioner Deremo, seconded by Commissioner Smith, to approve the guidelines and have them attached to the minutes. Motion Carried, 6-0.

XV. Future Meeting Dates

June 11, 2008
September 16, 2008
December 9, 2008

XVI. Public Comment

Larry Horwitz, Economic Alliance for Michigan

XVII. Review of Commission Work Plan

A. Commission Discussion

Ms. Rogers provided a brief overview of the draft Work Plan (Attachment P).

B. Commission Action

Motion by Commissioner Smith, seconded by Commissioner Young, to accept the Work Plan as amended. Motion Carried, 6-0.

XVIII. Adjournment

Motion by Commissioner Keshishian, seconded by Commissioner Deremo, to adjourn the meeting at 3:23 p.m. Motion Carried.

Dzelag Attachment
Attachment A

University of Michigan
Health System

Douglas L. Strong
Director & Chief Executive Officer
University of Michigan Hospitals and Health Centers
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March 11, 2008

Ms. Norma Hagenow
CON Commission Chairperson
Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Surgical O-Arm Classification Decision

Dear Ms Hagenow:

The University of Michigan Health System (UMHS) received a decision on March 7, 2008 from the Michigan Department of Community Health (MDCH), Certificate of Need (CON) Section regarding the classification of a piece of fluoroscopy equipment used for image guidance during specific surgical procedures. At the outset, UMHS would like to thank the members of the CON Section for their attention and diligence related to this matter. However, UMHS disagrees with the decision to classify this piece of surgical equipment in the same category as a Computed Tomography (CT) scanner.

The O-arm is a machine designed to allow a surgeon to see where screws are being placed during certain complex orthopedic or neurosurgical procedures. It is used only a few times a week. Indeed, our physicians estimate that it will only be used 200-300 times per year. This is not a diagnostic technology and is only used as a guidance mechanism.

This decision comes as an unfortunate surprise to this institution as it was our understanding, based on analysis from the Food and Drug Administration that this piece of equipment is not a CT scanner, but rather a mobile x-ray system. Specifically, this is an intra-operative navigation tool being added to an already existing image guided surgery configuration which is not covered under CON regulations. This equipment is not, and could not, be used as a diagnostic CT scanner; the low contrast imaging quality is well below the diagnostic quality requirements of a CT scanner.

UMHS has a long standing history of supporting the CON process, but we truly feel it would be an error to classify the O-Arm as a CT scanner. We stand ready to work with you and with the MDCH to resolve this matter.

Sincerely,

Douglas L. Strong
Director & Chief Executive Officer

Summary of February 6, 2008 Public Hearing Comments: Computed Tomography (CT) Scanners

Computed Tomography (CT) Scanners

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Jean Aldrich, CMPE	Association of Otolaryngology Administrators, Private Practice: Eye & ENT Specialists		Does not support: 1. Trust that the public would be in support of the physicians' position of changing the CON language to be much less restrictive, if restricted at all.	*CON is not the place to regulate over-utilization and cost concerns…From my research, regulating the availability of a service has not resulted in decreased cost or utilization. When deciding public or private healthcare policies, the patient care and satisfaction must be the guiding principles on any decision. Providing an opportunity for patients to receive care and treatment in a more timely fashion increases compliance, improves outcomes, and results in patient's trust and satisfaction in the health care system. I am appalled that we have provided a MI-based company with opportunities to grow their business foundation in Ann Arbor; however we have not allowed them complete access to the MI market due to CON regulations.*
Amy Barkholz	Michigan Health and Hospital Association (MHA)		Does not support: 1. It is not feasible for the O-arm to be regulated in the same way as a CT scanner. The MHA asks that the Department act quickly to determine whether or not this machine falls within	*The O-arm can only be used for guidance during specific surgical procedures and cannot be used as a diagnostic CT scanner. Physicians at the University of Michigan Health System (UMHS) estimate that it will be*

			the CT standards. If the department determines it is within the CT standards, the MHA asks the CON Commission to approve additional language in the CT standards currently before the Commission to accommodate the use of this specialized equipment.	*used about 200-300 times per year, so it is not practical to subject it to the same volume standards as a CT scanner because to do so would diminish a facility's ability to provide full access to CT services and O-arm technology.*
Jesse Bernstein	Ann Arbor Area Chamber of Commerce		Does not support: 1. Oppose CON regulation of medical equipment valued below $500,000.	*Following analysis of the CON threshold applied to certain low cost scanners, such as Xoran's MiniCAT, we realize how regulation can impede our growth in the healthcare industry and the service our physicians can provide their patients. We find it puzzling that MI maintains a regulation on low cost specialty-use CT scanners that 47 other states either don't implement or have abolished altogether.*
Dennis I. Bojrab, MD	Michigan Otolaryngology Society		Does not support: 1. The proposed language fails to consider the important and necessary use of low-dose, low-cost specialty CT scanners designed specifically for use by ENT physicians in their own office. Encourage you to exempt specialty use CT scanners from the CON process adding the following language to the Section 2(i) definitions of the proposed CT standards: "For	*The failure of our state to consider these limited use CT scanners has placed MI behind 47 other states in being able to provide lower cost, high quality imaging, and better access to our patients. Furthermore, it is creating a professional gap between ENT physicians in Michigan and those within the rest of the nation.*

			purposes of these standards, the (CT scanner) term does not include a CT scanner system that both generates a peak power output of 5 kilowatts or less and costs less than $500,000."	
Aaron Duberstein	M.D.		Does not support: 1. Encourage you to exempt specialty use CT scanners from the CON process adding the following language to the Section 2(i) definitions of the proposed CT Standards: "For purposes of these standards, the (CT scanner) term does not include a CT scanner system that both generates a peak power output of 5 kilowatts or less and costs less than $500,000."	*Given the current economic climate and the fact that Michigan faces a physician shortage, restrictions on in-office specialty CT scanners is a negative incentive for retaining residents for future practice in this state, even residents such as my colleagues and I who have chosen to train here.*
Michael S. Fozo	Lakeshore Ear, Nose and Throat PC		Does not support: 1. The proposed language fails to consider the important and necessary use of low-dose, low-cost specialty CT scanners designed specifically for use by ENT physicians in their own office. Encourage you to exempt specialty use CT scanners from the CON process adding the following language to the Section 2(i) definitions of the proposed CT Standards: For purposes of these standards, the (CT scanner) term does not include a CT scanner system that both generates	*The failure of our state to consider these limited use CT scanners has placed MI behind 47 other states in being able to provide lower cost, high quality imaging, and better access to our patients. Furthermore, it is creating a professional gap between ENT physicians in Michigan and those within the rest of the nation.*

			a peak power output of 5 kilowatts or less and costs less than $500,000."	
James E. Heisel, M.D.	Foote Hospital Radiology Department, Jackson, MI	Support: 1. The CON requirement currently in place is a valuable asset to the State of Michigan and to the patients of our State. It effectively prevents the oversupply of CT scanners and MRI machines and by doing so, it reduces the over utilization of the expensive tests performed by them. If the regulations where changed to allow the purchase of these smaller CT scanners for in-office use, the number of tests would increase, with the high likelihood that the extra tests would be medically unnecessary. It is well known and also well documented in health care literature that self referral of testing procedures is a major cause of excess health care costs.		*The Michigan economy cannot afford higher health care costs at a time when we need badly to lower health care costs to improve the business climate. The desire for this change is purely economic, designed to create a business opportunity for the Xoran Company and to allow ENT physicians or other office based practitioners to begin to create new sources of revenue for their practices. There is no patient benefit of substance. The miniCAT by design will produce inferior images to the ones on a regular scanner with a potential for misdiagnosis. The argument for point of service care in the office fails to take into account the fact that the most important factor in any imaging test might be missing; the expert review and interpretation of the test by a qualified radiologist.*
Paul Theodore Hoff	Michigan Otolaryngology Surgery Associates		Does not support: 1. Clearly, MI needs to adopt the guidelines followed by nearly every other state, and allow for low dose office CT scanners for ENT practices.	*I have been practicing in MI for 9 years and have been frustrated by my inability to offer my patients convenient, cutting edge in-office CT scanning. What is most ironic is that the technology of low dose office scanning was developed right here in MI (Xoran).*
John Jacobs, MD			Does not support: 1. Joining the other	*Picture yourself as a patient requiring a CT*

			47 states that allow office CT scans is improved appropriate care efficiently delivered.	*scan for a sinus problem. You have already taken time off from work to see the doctor. Do you really want to take more time from work to get a hospital CT scan knowing that it exposes you to unnecessary levels of radiation exposure and that you are in competition with hospitalized patients for the same resource?*
Dennis McCafferty	The Economic Alliance for Michigan (EAM)	Support: Strongly agree with the position that all CT scanners should continue to be subject to CON. Also support and endorse the many other improvements in the CT Scanner CON standards proposed by the SAC and accepted by the Commission, including: 1. The minimum annual volume number of scan equivalents is unchanged at 7500. 2. Replacement for existing CT Scanners can only be done if current machine has met this minimum annual volume at some time since its inception AND now is providing at least 5,000 CT equivalents. 3. Projecting the need for new CT scanner sites based on actual, historically referral volumes, that can be verified by MDCH through its annual survey. 4. That projection of need for new CT scanners cannot use referrals that would result in lowering an existing CT scanner below its minimum CON volume requirements. 5. Approval of a Demonstration Project for Special Use Portable CTs, limited to major trauma centers that have experienced staff on site to maintain, operate and interpret the results. The scans on these special use units will not be counted as part of the hospitals other CT scanner equivalent scan totals. 6. Continued CON regulation of dental office CT at the same annual minimum volume and services approved by the Commission in 2006.		*The members of EAM oppose efforts by some to exempt Specialty Use CT units from CON regulations. This issue was dealt with by the SAC. The manufacturer of these machines was given ample opportunity to present its reasons for exempting these units. Absent clinical evidence that this new technology will provide value to the patients by improving access, lowering cost or improving quality of care, we see no reason for exempting these specialty use CT units from the CON standards.*

Robert Meeker	Spectrum Health	Support: Support the recommended changes to the CT Standards. In particular, Spectrum Health supports the following recommendations of the CTSAC: 1. Continued CON coverage of CT 2. Continuation of the minimum volume requirement of 7,500 CTEs 3. Revisions to the Relocation criteria which allow relocation of either an entire CT service or a single CT unit 4. Revision to the definition of Replace an Existing CT Scanner to include only projects requiring a change in the radiation safety certificate 5. Revisions to the data commitment process to assure that the applicant must be able to document that the CT referrals committed actually occurred, and the CT referrals committed, if actually referred to the new CT service, would not result in the existing CT service(s) falling below their minimum volume requirements. Do not create an undue burden on CT providers by replicating the existing MRI database. 6. Provisions for Level I & II Trauma Centers to obtain special use CT scanners without meeting the minimum volume requirement. 7. Provisions for dedicated pediatric CT scanners and additional weights for pediatric scans performed on general purpose CT scanners, with special attention to limiting radiation exposure for pediatric patients.		*Spectrum Health appreciates the opportunity to comment on the proposed CON Review Standards for CT, and we urge the CON Commission to approve them in final form at the meeting on March 11, 2008.*
Michael Nosanov, M.D.	Eye & ENT Specialists, PLC		Does not support: 1. Feel the inability to provide our patients with the most up to date care not only has the potential to delay diagnosis and treatment of my patient with sinus and other Head & Neck disorders, but can effect outcomes, cause delay in return to	*I also believe that the lack of this service will impair our ability to recruit and retain qualified providers in our state. The issue of the potential for over utilization is really unfounded. I believe that we tend to under utilize this type of exam as it would be too inconvenient, costly, and may have higher*

			work and increase the overall health care costs.	*radiation exposure risks. In reality, it would be appropriately used to provide the most efficient and timely care.*
Stephen Rapundalo, PhD	MichBio		Does not support: 1. Support the long-standing position of Xoran Technologies, a MichBio member, in their quest to seek relief from current regulatory restrictions that prohibit the sale of specialty CT scanners in the state. Ask the CON Commission to adopt language similar to that recently approved by West Virginia that specifically exempts low-dose, low-cost CT scanners from CON regulations. Regulations should not include CT scanner systems that generate 8804; 5 KW of peak power and cost less than $500,000.	*Allowing access to low-cost, low-dose CT scanners should provide a more efficient, safe and cost-effective delivery of quality healthcare. There appears to be no rationale for separating specialty CT scanners from other low-cost medical equipment used in-office that are currently not regulated under CON. MichBio, as the statewide life sciences and biotechnology industry association, supports measures that will strengthen Michigan's competitiveness and maximizes the marketplace for our companies.*
Caroline Ruddell	Michigan Dental Association (MDA)	Support: 1. We supported the current standards because we felt it gave our members the option to utilize this important technology if they did not want to wait until the review of the CT standards was complete. However, current CON regulations are certainly hindering Michigan citizens' access to this advancement in dental technology.	Does not support: 1. MDA would like to respectfully request that dental CT be exempted from CT standards.	*The MDA recognizes the role of the CON commission is to regulate cost, quality and access to healthcare in MI. However, the cost of a dental CT is very different than medical CT and at roughly $200,000 they are less than many unregulated pieces of medical equipment and cost far less than medical CT. CON does not regulate any other piece of medical equipment that is so inexpensive. In addition, CON does not regulate the*

				digital panorex, which is the same price, provides the same type of images, and is nearly interchangeable with a Dental CT.
Steven Szelag	University of Michigan Health System (UMHS)		Does not support: 1. We understand that the SAC for CT services have recently completed their 6-month review of the standards and have presented their final report to the CON Commission. We do not wish to re-open the CT review process. However, UMHS recommends further refinement of the definition of a CT scanner so that technology like the C-arm and the O-arm, can be similarly excluded like other imaging modalities used for treatment planning.	*UMHS acquired the first surgical O-arm in the State Of Michigan in October, 2007. Our physicians estimate that it will only be used 200-300 times per year. It is not a diagnostic technology, but is only used for guidance during specific surgical procedures. During the radiation safety registration process, the MDCH decided to treat this piece of equipment as a CT scanner, requiring a CON. This was a surprise to hospital administration as it was our understanding, based on analysis from the FDA that this piece of equipment is not a CT scanner, but rather a mobile x-ray system.*
Jeffrey S. Weingarten, MD	Physician		Does not support: 1. The proposed language fails to consider the important and necessary use of low-dose, low-cost specialty CT scanners designed specifically for use by ENT physicians in their own office. Encourage you to exempt specialty use CT scanners from the CON process adding the following language to the Section 2(i) definitions of the proposed CT Standards: "For purposes of these	*The definition change will place MI in the same category as the 47 other states that do not regulate these specialty use CT scanners and will give ENT physicians the ability to choose to acquire this much needed technology. This is the least restrictive way of lowering cost, providing quality, and improving access to healthcare in the state and the best way for ENT physicians to ensure that our patients and citizens get the necessary care they*

			standards, the (CT scanner) term does not include a CT scanner system that both generates a peak power output of 5 kilowatts or less and costs less than $300,000." MSMS supports the loss of the CON requirement for the miniCAT technology.	*deserve.*
Howard Yerman, MD			Does not support: 1. The proposed language fails to consider the important and necessary use of low-dose, low-cost specialty CT scanners designed specifically for use by ENT physicians in their own office. Encourage you to exempt specialty use CT scanners from the CON process adding the following language to the Section 2(i) definitions of the proposed CT Standards: "For purposes of these standards, the (CT scanner) term does not include a CT scanner system that both generates a peak power output of 5 kilowatts or less and costs less than $500,000."	*The definition change will place MI in the same category as the 47 other states that do not regulate these specialty use CT scanners and will give ENT physicians the ability to choose to acquire this much needed technology. This is the least restrictive way of lowering cost, providing quality, and improving access to healthcare in the state and the best way for ENT physicians to ensure that our patients and citizens get the necessary care they deserve. **In addition to the information noted above, please consider the fact that use of low-dose in office sinus CT imaging will likely reduce use of older imaging modalities (plain sinus x-rays), and thus allow more expeditious, cost effective, quality care.***
Matthew W. Jordan	Xoran Technologies, Inc.		Does not support: 1. Simply put, the requirement that all CT CON applicants, regardless of the type of equipment, demonstrate 7500 equivalent CT	*Our main product is the MiniCAT, a low-cost, low-radiation dose specialty CT scanner designed for in-office use. By bringing a $230,000 limited use specialty*

			scans in order to achieve CON approval, effectively, prohibits any ENT physician and most hospitals from acquiring a low-cost, low-dose specialty CT scanner. Xoran urges the CON Commission to make a change to the proposed CON CT Standards now before the Commission. In the definition of a CT scanner in Section 2(i), the following language should be added: "The term (CT Scanner) does not include CT scanner systems that both generate a peak power output of 5 kilowatts or less and costs less than $500,000."	*CT scanner to ENT physicians in their office, patients and physicians have an opportunity to achieve better, faster, and safer diagnostic imaging that is vital to treatment. And yet despite the promise of this technology and its availability in 47 other states without the requirements of a CON application, MI remains just one of three states that effectively prohibit this in-office specialty CT due to restrictive CON regulations. The end result is that ENT physicians in MI are prohibited from acquiring these specialty CT scanners for their offices, patients are blocked from access to lower radiation dose CT scanning despite national calls to limit x-ray exposure, and a MI company, Xoran is unable to sell its equipment in its own home state.*
<u>The Department supports the proposed standards.</u> No additional change is recommended based on the CT comments received during public hearing.				

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.

(2) CT scanner is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, ~~and~~ 16, 17, 21, AND 22, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) ~~(4)~~ The Department shall use sections 193 and 2014, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 18 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of aN EXISTING CT scanner service" means obtaining possession or control of aN EXISTING FIXED OR MOBILE CT scanner service ~~and its~~ OR EXISTING CT SCANNER ~~unit~~(s)~~, whether fixed or mobile,~~ by contract, ownership, or ~~otherwise~~OTHER COMPARABLE ARRANGEMENT. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit, AND PERFORMED IN MICHIGAN.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(g) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(h) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 2115.

(i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ~~and~~ ultrasound computed tomographic systems, AND CT

SIMULATORS USED SOLELY FOR TREATMENT PLANNING PURPOSES IN CONJUNCTION WITH AN MRT UNIT.

~~(j) "CT scanner equipment," for purposes of sections 3 and 6 of these standards, means the equipment necessary to perform CT scans. It does not include any construction or renovations activities associated with the installation of the CT scanner, or service or maintenance contracts which under generally accepted accounting principles are properly chargeable as an expense of operation.~~

(J) "CT SCANNER SERVICES" MEANS THE CON-APPROVED UTILIZATION OF A CT SCANNER(S) AT ONE SITE IN THE CASE OF A FIXED CT SCANNER SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE CT SCANNER SERVICE.

(K) "DEDICATED PEDIATRIC CT" MEANS A FIXED CT SCANNER ON WHICH AT LEAST 70% OF THE CT PROCEDURES ARE PERFORMED ON PATIENTS UNDER 18 YEARS OF AGE.

(~~k~~L) "Dental CT EXAMINATIONS~~images~~" means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.

(~~l~~M) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

(~~m~~N) "Department" means the Michigan Department of Community Health (MDCH).

~~(n) "Driving time," for purposes of these standards, means the driving time in minutes as identified by use of mapping software that is verifiable by the Department.~~

(o) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(P) "EXISTING CT SCANNER SERVICE" MEANS THE UTILIZATION OF A CON-APPROVED AND OPERATIONAL CT SCANNER(S) AT ONE SITE IN THE CASE OF A FIXED CT SCANNER SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE CT SCANNER SERVICE.

(Q) "EXISTING CT SCANNER" MEANS A CON-APPROVED AND OPERATIONAL CT SCANNER USED TO PROVIDE CT SCANNER SERVICES.

(R) "EXISTING MOBILE CT SCANNER SERVICE" MEANS A CON-APPROVED AND OPERATIONAL CT SCANNER AND TRANSPORTING EQUIPMENT OPERATED BY A CENTRAL SERVICE COORDINATOR SERVING TWO OR MORE HOST SITES.

(~~p~~S) "Expand aN EXISTING CT scanner service" means the addition of one or more CT scanners at an existing CT scanner service.

(~~q~~T) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(~~r~~U) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

(V) "HOSPITAL-BASED PORTABLE CT SCANNER" MEANS A CT SCANNER CAPABLE OF BEING TRANSPORTED INTO PATIENT CARE AREAS (I.E., ICU ROOMS, OPERATING ROOMS, ETC.) TO PROVIDE HIGH-QUALITY IMAGING OF CRITICALLY ILL PATIENTS.

(~~s~~W) "Host SITE~~facility~~" means the site at which a mobile CT scanner is AUTHORIZED~~located in order~~ to provide CT scanner services.

(~~t~~X) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing CT scanner service or the renewal of a lease.

(~~u~~Y) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~v~~Z) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(~~w~~AA) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(~~x~~BB) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(~~y~~CC) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(DD) "PEDIATRIC PATIENT" MEANS ANY PATIENT LESS THAN 18 YEARS OF AGE.

(EE) "RELOCATE A FIXED CT SCANNER" MEANS A CHANGE IN THE LOCATION OF A FIXED CT SCANNER FROM THE EXISTING SITE TO A DIFFERENT SITE WITHIN THE RELOCATION ZONE.

(~~z~~FF) "Relocate an existing CT scanner service" means a change in the geographic location of an existing fixed CT scanner service ~~and its unit(s)~~ from an existing site to a different site.

(~~aa~~GG) "Relocation zone," ~~for purposes of these standards,~~ means a site that is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county.

(~~bb~~HH) "Replace~~/upgrade~~ aN EXISTING CT scanner" means an equipment change OF AN EXISTING CT SCANNER, THAT REQUIRES A CHANGE IN THE RADIATION SAFETY CERTIFICATE, proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion, AT THE SAME GEOGRAPHIC LOCATION.

(~~cc~~II) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(JJ) "SEDATED PATIENT" MEANS A PATIENT THAT MEETS ALL OF THE FOLLOWING:

(I) PATIENT UNDERGOES PROCEDURAL SEDATION AND WHOSE LEVEL OF CONSCIOUSNESS IS EITHER MODERATE SEDATION OR A HIGHER LEVEL OF SEDATION, AS DEFINED BY THE AMERICAN ASSOCIATION OF ANESTHESIOLOGISTS, THE AMERICAN ACADEMY OF PEDIATRICS, THE JOINT COMMISSION ON THE ACCREDITATION OF HEALTH CARE ORGANIZATIONS, OR AN EQUIVALENT DEFINITION.

(II) WHO REQUIRES OBSERVATION BY PERSONNEL, OTHER THAN TECHNICAL EMPLOYEES ROUTINELY ASSIGNED TO THE CT UNIT, WHO ARE TRAINED IN CARDIOPULMONARY RESUSCITATION (CPR) AND PEDIATRIC ADVANCED LIFE SUPPORT (PALS).

(KK) "SPECIAL NEEDS PATIENT" MEANS A NON-SEDATED PATIENT, EITHER PEDIATRIC OR ADULT, WITH ANY OF THE FOLLOWING CONDITIONS: DOWN SYNDROME, AUTISM, ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD), DEVELOPMENTAL DELAY, MALFORMATION SYNDROMES, HUNTER'S SYNDROME, MULTI-SYSTEM DISORDERS, PSYCHIATRIC DISORDERS, AND OTHER CONDITIONS THAT MAKE THE PATIENT UNABLE TO COMPLY WITH THE POSITIONAL REQUIREMENTS OF THE EXAM.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service other than a dental CT scanner service OR HOSPITAL-BASED PORTABLE CT SCANNER SERVICE

Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the following, as applicable:

(1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the following:

(a) The proposed site is a hospital licensed under Part 215 of the Code.

(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.

(2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1), proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT

equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner service

Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the following, as applicable:

(1) An applicant is proposing a fixed CT scanner service for the sole purpose of PERFORMING~~generating~~ dental CT~~ct~~ EXAMINATIONS~~images~~.

(2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

(3) An applicant proposing to initiate a dental CT scanner service shall project an operating level of at least 200 dental CT EXAMINATIONS~~images~~ per year for the second 12-month period after beginning operation of the dental CT scanner.

(4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(5) The applicant has demonstrated to the satisfaction of the Department that the dental CT EXAMINATIONS~~images~~ generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

Section 5. Requirements FOR APPROVAL FOR APPLICANTS PROPOSING to expand aN EXISTING CT scanner service OTHER THAN A DENTAL CT SCANNER SERVICE OR HOSPITAL-BASED PORTABLE CT SCANNER SERVICE

Sec. 5. (1) ~~If a~~An applicant propos~~ING~~es to expand aN EXISTING fixed CT scanner service~~, the applicant~~ shall demonstrate~~ each of the following:~~

~~(a)The applicant shall project an average operating level of at least 7,500 CT equivalents for each fixed CT scanner, existing and proposed, operated by the applicant for the second 12-month period after initiation of operation of each additional CT scanner.~~

~~(b)A~~ THAT All of the applicant's fixed CT scanners, EXCLUDING CT SCANNERS APPROVED PURSUANT TO SECTIONS 13 AND 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) AN APPLICANT PROPOSING TO EXPAND AN EXISTING FIXED CT SCANNER SERVICE APPROVED PURSUANT TO SECTION 17 SHALL DEMONSTRATE THAT ALL OF THE APPLICANT'S DEDICATED PEDIATRIC CT SCANNERS HAVE PERFORMED AN AVERAGE OF AT LEAST 3,000 CT EQUIVALENTS PER DEDICATED PEDIATRIC CT SCANNER FOR THE MOST RECENT

CONTINUOUS 12-MONTH PERIOD PRECEDING THE APPLICANT'S REQUEST. IN COMPUTING THIS AVERAGE, THE DEPARTMENT WILL DIVIDE THE TOTAL NUMBER OF CT EQUIVALENTS PERFORMED BY THE APPLICANT'S TOTAL NUMBER OF DEDICATED PEDIATRIC CT SCANNERS, INCLUDING BOTH OPERATIONAL AND APPROVED BUT NOT OPERATIONAL DEDICATED PEDIATRIC CT SCANNERS.

(~~2~~3) If an applicant proposes to expand aN EXISTING mobile CT scanner service, the applicant shall demonstrate ~~each of the following:~~

~~(a) The applicant shall project an operating level of at least 4,000 CT equivalents for each existing and proposed mobile CT scanner for the second 12-month period after beginning operation of each additional CT scanner.~~

~~(b)~~ A THAT All of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

SECTION 6. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO EXPAND AN EXISTING DENTAL CT SCANNER SERVICE

SEC. 6. AN APPLICANT PROPOSING TO EXPAND AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT ALL OF THE APPLICANT'S DENTAL CT SCANNERS HAVE PERFORMED AN AVERAGE OF AT LEAST 300 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER FOR THE MOST RECENT CONTINUOUS 12-MONTH PERIOD PRECEDING THE APPLICANT'S REQUEST. IN COMPUTING THIS AVERAGE, THE DEPARTMENT WILL DIVIDE THE TOTAL NUMBER OF DENTAL CT EXAMINATIONS PERFORMED BY THE APPLICANT'S TOTAL NUMBER OF FIXED DENTAL CT SCANNERS, INCLUDING BOTH OPERATIONAL AND APPROVED BUT NOT OPERATIONAL FIXED DENTAL CT SCANNERS.

Section ~~7~~6. Requirements for APPROVAL FOR applicaNTS~~tions~~ proposing to replace~~/upgrade~~ aN EXISTING CT scanner OTHER THAN A DENTAL CT SCANNER OR HOSPITAL-BASED PORTABLE CT SCANNER

Sec. ~~7~~6. ~~In order to be approved, a~~An applicant proposing to replace~~/upgrade~~ an existing CT scanner shall demonstrate each of the following, as applicable:

~~(1) A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital shall demonstrate each of the following:~~

~~(a) The proposed site is a hospital licensed under Part 215 of the Code.~~

~~(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.~~

~~(c) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.~~

(~~2~~1) An applicant, other than an applicant meeting all of the applicable requirements of subsection ~~(1)~~(A), (B) OR (C) BELOW, proposing to replace~~/upgrade~~ an existing fixed CT scanner shall demonstrate that the FIXED CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 7,500 CT EQUIVALENTS PER FIXED CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.~~volume of CT equivalents, during the 12-month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 7,500 CT equivalents if the applicant operates only one fixed CT scanner, or an average of 7,500 CT equivalents for each fixed CT scanner if the applicant operates more than one fixed CT scanner at the same site.~~

(A) A HOSPITAL PROPOSING TO REPLACE AN EXISTING CT SCANNER WHICH IS THE ONLY FIXED CT SCANNER OPERATED AT THAT SITE BY THE HOSPITAL SHALL DEMONSTRATE EACH

OF THE FOLLOWING:

(I) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(II) THE HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS.

(III) THE REPLACEMENT CT SCANNER WILL BE LOCATED AT THE SAME SITE AS THE CT SCANNER TO BE REPLACED.

(B) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER SHALL BE EXEMPT ONCE FROM THE VOLUME REQUIREMENTS IF THE EXISTING CT SCANNER DEMONSTRATES THAT IT MEETS ALL OF THE FOLLOWING:

(I) THE EXISTING CT SCANNER HAS PERFORMED AT LEAST 5,000 CT EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(II) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(III) THE EXISTING CT SCANNER HAS AT ONE TIME MET ITS MINIMUM VOLUME REQUIREMENTS.

(C) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER ON AN ACADEMIC MEDICAL CENTER CAMPUS, AT THE SAME SITE, SHALL BE EXEMPT ONCE, AS OF THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS FOR REPLACEMENT IF THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(~~3~~2) An applicant proposing to replace~~/upgrade~~ an existing mobile CT scanner(s) shall demonstrate that the MOBILE CT SCANNER(S) PERFORMED ~~volume of CT equivalents, during the 12-month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was~~ at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network, IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(3) AN APPLICANT PROPOSING TO REPLACE AN EXISTING DEDICATED PEDIATRIC CT SCANNER(S) SHALL DEMONSTRATE THAT THE DEDICATED PEDIATRIC CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 2,500 CT EQUIVALENTS PER DEDICATED PEDIATRIC CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(4) An applicant under this section shall demonstrate that the EXISTING CT scanner(s) proposed to be replaced~~/upgraded~~ is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement~~/upgraded~~ CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

SECTION 8. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO REPLACE AN EXISTING DENTAL CT SCANNER

SEC. 8. AN APPLICANT PROPOSING TO REPLACE AN EXISTING DENTAL CT SCANNER SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED DENTAL CT SCANNER SHALL DEMONSTRATE THAT THE FIXED DENTAL CT SCANNER(S) PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(2) AN APPLICANT UNDER THIS SECTION SHALL DEMONSTRATE THAT THE EXISTING DENTAL CT SCANNER(S) PROPOSED TO BE REPLACED IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES, OR, THAT THE EXISTING EQUIPMENT CLEARLY POSES A THREAT TO THE SAFETY OF THE PUBLIC, OR THAT THE PROPOSED REPLACEMENT DENTAL CT SCANNER OFFERS TECHNOLOGICAL IMPROVEMENTS WHICH ENHANCE QUALITY OF CARE, INCREASE EFFICIENCY, AND/OR REDUCE OPERATING COSTS AND PATIENT CHARGES.

Section 97. Requirements for approval for applicants proposing to relocate an existing CT scanner service AND/OR CT SCANNER(S) OTHER THAN AN EXISTING DENTAL CT SCANNER SERVICE AND/OR DENTAL CT SCANNER(S) OR HOSPITAL-BASED PORTABLE CT SCANNER(S)

Sec. 97. (1) An applicant proposing to relocate ANits existing FIXED CT scanner service and its unit(s) shall demonstrate that the proposed project meets all of the following:

(1) The CT scanner service and its unit(s) to be relocated is a fixed CT scanner unit(s).

(A2) The EXISTING FIXED CT scanner service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(B3) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 5 OR 7, AS APPLICABLE, HAVE BEEN MET.The proposed project will not result in the replacement of the CT scanner unit(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.

(4) The proposed project will not result in an increase in the number of fixed unit(s) being operated by the CT scanner service that is proposed to be relocated.

(5) The proposed site to which the CT scanner service is proposed to be relocated is in the relocation zone.

(D6) The CT scanner service and its unit(s) to be relocated performed at least an average of 7,500 CT equivalents per fixed SCANNERunit in the most recent 12-month period, or most recent annualized 6-month period, for which the Department has verifiable data.

(E7) The applicant agrees to operate the CT scanner service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 193 of these standards.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED CT SCANNER(S) OF AN EXISTING CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING CT SCANNER SERVICE FROM WHICH THE CT SCANNER(S) IS TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 5 OR 7, AS APPLICABLE, HAVE BEEN MET.

(D) EACH EXISTING CT SCANNER AT THE SERVICE FROM WHICH A SCANNER IS TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 7,500 CT EQUIVALENTS PER FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE CT SCANNER(S) AT THE PROPOSED SITE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

SECTION 10. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO RELOCATE AN EXISTING DENTAL CT SCANNER SERVICE AND/OR DENTAL CT SCANNER(S)

SEC. 10. (1) AN APPLICANT PROPOSING TO RELOCATE AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING FIXED DENTAL CT SCANNER SERVICE TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTH AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 6 OR 8, AS APPLICABLE, HAVE BEEN MET.

(D) THE DENTAL CT SCANNER SERVICE TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE DENTAL CT SCANNER SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED DENTAL CT SCANNER(S) OF AN EXISTING DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING DENTAL CT SCANNER SERVICE FROM WHICH THE DENTAL CT SCANNER(S) IS TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(C) THE REQUIREMENTS OF SECTIONS 6 OR 8, AS APPLICABLE HAVE BEEN MET.

(D) EACH EXISTING DENTAL CT SCANNER AT THE SERVICE FROM WHICH A SCANNER IS TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 200 DENTAL CT EXAMINATIONS PER FIXED DENTAL CT SCANNER IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(E) THE APPLICANT AGREES TO OPERATE THE DENTAL CT SCANNER(S) AT THE PROPOSED SITE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

Section 118. Requirements for approval for applicants proposing to acquire an existing CT scanner service ~~and its unit(s)~~ OR AN EXISTING CT SCANNER(S) OTHER THAN AN EXISTING DENTAL CT SCANNER SERVICE AND/OR AN EXISTING DENTAL CT SCANNER(S) OR HOSPITAL-BASED PORTABLE CT SCANNER(S)

Sec. 118. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service ~~and its unit(s)~~ shall demonstrate that a proposed project meets all of the following:

(~~1~~A) THE REQUIREMENTS OF SECTIONS 5, 7, OR 9, AS APPLICABLE, HAVE BEEN MET.~~The project will not result in the replacement of the CT scanner unit at the CT scanner service to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.~~

~~(2) The project will not result in a change in the site at which the existing CT scanner service and its unit(s) is operated unless the proposed project meets the requirements of Section 7.~~

~~(3) The project will not change the number of CT scanner unit(s) at the site of the CT scanner service being acquired unless the applicant demonstrates that project is in compliance with the requirements of Section 5 as applicable.~~

(~~4~~B) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner service, for which a final decision has not been issued after ~~the effective date of these standards~~JUNE 4, 2004, an existing CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service ~~and its unit(s)~~ shall be operating at the applicable volume requirements set forth in Section 19~~3~~ of these standards in the second 12 months after the date the service ~~and its unit(s)~~ is acquired, and annually thereafter.

(~~5~~C) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, ~~except the first application approved pursuant to subsection (4), for which a final decision has not been~~

~~issued after the effective date of these standards,~~ an applicant shall be required to demonstrate that the CT scanner service ~~and its unit(s)~~ to be acquired performed at least 7,500 CT equivalents in the most recent 12-month period~~, or most recent annualized 6-month period,~~ for which the Department has verifiable data.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE CT SCANNER(S) OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 5, 7 OR 9, AS APPLICABLE, HAVE BEEN MET.
(B) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED OR MOBILE CT SCANNER(S) OF AN EXISTING FIXED OR MOBILE CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE FIXED OR MOBILE CT SCANNER(S) TO BE ACQUIRED PERFORMED AT LEAST 7,500 CT EQUIVALENTS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

SECTION 12. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING DENTAL CT SCANNER SERVICE OR AN EXISTING DENTAL CT SCANNER(S)

SEC. 12. (1) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT A PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 6, 8, OR 10, AS APPLICABLE, HAVE BEEN MET.
(B) FOR AN APPLICATION FOR THE PROPOSED FIRST ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, FOR WHICH A FINAL DECISION HAS NOT BEEN ISSUED AFTER THE EFFECTIVE DATE OF THESE STANDARDS, AN EXISTING DENTAL CT SCANNER SERVICE TO BE ACQUIRED SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENT APPLICABLE TO THE SELLER/LESSOR ON THE DATE THE ACQUISITION OCCURS. THE DENTAL CT SCANNER SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.
(C) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE CT SCANNER SERVICE TO BE ACQUIRED PERFORMED AT LEAST 200 DENTAL CT EXAMINATIONS IN THE MOST RECENT 12-MONTH PERIOD, FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED DENTAL CT SCANNER(S) OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:
(A) THE REQUIREMENTS OF SECTIONS 6, 8, OR 10, AS APPLICABLE, HAVE BEEN MET.
(B) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED DENTAL CT SCANNER(S) OF AN EXISTING FIXED DENTAL CT SCANNER SERVICE, AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE FIXED DENTAL CT SCANNER(S) TO BE ACQUIRED PERFORMED AT LEAST 200 DENTAL CT EXAMINATIONS IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

SECTION 13. PILOT PROGRAM REQUIREMENTS FOR APPROVAL OF A HOSPITAL-BASED PORTABLE CT SCANNER FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION

SEC. 13. AS A PILOT PROGRAM, AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE A HOSPITAL-BASED PORTABLE CT SCANNER SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICANT IS LIMITED TO THE INITIATION, EXPANSION, REPLACEMENT, OR ACQUISITION OF NO MORE THAN TWO HOSPITAL-BASED PORTABLE CT SCANNERS.

(2) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(3) THE HOSPITAL HAS BEEN CERTIFIED AS A LEVEL I OR LEVEL II TRAUMA FACILITY BY THE AMERICAN COLLEGE OF SURGEONS.

(4) THE APPLICANT AGREES TO OPERATE THE HOSPITAL-BASED PORTABLE CT SCANNER IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 19 OF THESE STANDARDS.

(5) THE APPROVED HOSPITAL-BASED PORTABLE CT SCANNER WILL NOT BE SUBJECT TO CT VOLUME REQUIREMENTS.

(6) THE APPLICANT MAY NOT UTLIZE CT PROCEDURES PERFORMED ON A HOSPITAL-BASED PORTABLE CT SCANNER TO DEMONSTRATE NEED OR TO SATISFY CT CON REVIEW STANDARDS REQUIREMENTS.

(7) THE PROVISIONS OF SECTION 13 ARE PART OF A PILOT PROGRAM APPROVED BY THE CON COMMISSION AND SHALL EXPIRE AND BE OF NO FURTHER FORCE AND EFFECT, AND SHALL NOT BE APPLICABLE TO ANY APPLICATION WHICH HAS NOT BEEN SUBMITTED BY OCTOBER 1, 2008.

Section 14~~9~~. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, and acquisition

Sec. 14~~9~~. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 19~~3~~ of these standards.

(3) The approved PET/CT hybrid will not be subject to CT volume requirements.

(4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid SCANNER~~unit~~ to demonstrate need or to satisfy CT CON review standards requirements.

Section 15~~0~~. Additional requirements for approval of a mobile CT scanner service

Sec. 15~~0~~. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following:

(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile CT scanner service shall be included in the CON application submitted by the central service coordinator.

(c) The requirements of sections 3, 5, or 7~~6~~, as applicable, have been met.

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

(b) A separate CON application has been filed for each host facility.

(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner network shall demonstrate that approval of the application will not replace the CT scanner and transporting equipment unless the applicable requirements of Section 76 have been met.

Section 161. Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of PERFORMINGgenerating dental CT EXAMINATIONSimages exclusively for research

Sec. 161. (1) An applicant proposing a CT scanner used for the sole purpose of PERFORMINGgenerating dental CT EXAMINATIONSimages exclusively for research shall demonstrate each of the following:

(a) The applicant operates a dental radiology program in a certified dental school.

(b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of approval in Section 193(4).

(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with the requirements of sections 4(2), 4(4) and 4(5).

SECTION 17. REQUIREMENTS FOR APPROVAL OF AN APPLICANT PROPOSING TO ESTABLISH DEDICATED PEDIATRIC CT

SEC. 17. (1) AN APPLICANT PROPOSING TO ESTABLISH DEDICATED PEDIATRIC CT SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(A) THE APPLICANT SHALL HAVE EXPERIENCED AT LEAST 7,000 PEDIATRIC (< 18 YEARS OLD) DISCHARGES (EXCLUDING NORMAL NEWBORNS) IN THE MOST RECENT YEAR OF OPERATION.

(B) THE APPLICANT SHALL HAVE PERFORMED AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES IN THE MOST RECENT YEAR OF OPERATION.

(C) THE APPLICANT SHALL HAVE AN ACTIVE MEDICAL STAFF, AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT THAT INCLUDES, BUT IS NOT LIMITED TO, PHYSICIANS WHO ARE FELLOWSHIP-TRAINED IN THE FOLLOWING PEDIATRIC SPECIALTIES:

(I) PEDIATRIC RADIOLOGY (AT LEAST TWO)

(II) PEDIATRIC ANESTHESIOLOGY

(III) PEDIATRIC CARDIOLOGY

(IV) PEDIATRIC CRITICAL CARE

(V) PEDIATRIC GASTROENTEROLOGY

(VI) PEDIATRIC HEMATOLOGY/ONCOLOGY

(VII) PEDIATRIC NEUROLOGY

(VIII) PEDIATRIC NEUROSURGERY

(IX) PEDIATRIC ORTHOPEDIC SURGERY

(X) PEDIATRIC PATHOLOGY

(XI) PEDIATRIC PULMONOLOGY

(XII) PEDIATRIC SURGERY

(XIII) NEONATOLOGY

(D) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

(I) PEDIATRIC BONE MARROW TRANSPLANT PROGRAM
(II) ESTABLISHED PEDIATRIC SEDATION PROGRAM
(III) PEDIATRIC OPEN HEART PROGRAM

(2) AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (1) SHALL BE EXEMPT FROM MEETING THE REQUIREMENTS OF SECTION 3 OF THESE STANDARDS.

Section 182. Requirements for approval -- all applicants

Sec. 182. ~~An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. 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~~AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY 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~~.~~

Section 193. Project delivery requirements--terms of approval for all applicants

Sec. 193. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards

(b) Compliance with applicable safety and operating standards

(c) Compliance with the following quality assurance standards:

(i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(A) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(B) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to screening and interpretation if the applicant requires the screening of requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(iv) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis (either on-site or through telecommunication capabilities) to make the final interpretation.

(v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site or available through telecommunication

capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A) within 24 hours.

(vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency patients.

(viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(X) AN APPLICANT APPROVED UNDER SECTION 17 MUST BE ABLE TO PROVE THAT ALL RADIOLOGISTS, TECHNOLOGISTS AND NURSING STAFF WORKING WITH CT PATIENTS HAVE CONTINUING EDUCATION OR IN-SERVICE TRAINING ON PEDIATRIC LOW-DOSE CT. THE SITE MUST ALSO BE ABLE TO PROVIDE EVIDENCE OF DEFINED LOW-DOSE PEDIATRIC CT PROTOCOLS.

(~~x~~XI) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(A) not deny CT scanner services to any individual based on ability to pay or source of payment;

(B) provide CT scanning services to any individual based on the clinical indications of need for the service; and

(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(~~xi~~XII) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site ~~or unit~~ as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~xii~~XIII) Equipment to be replaced shall be removed from service.

(~~xiii~~IV) The applicant shall provide the Department with a notice stating the date the approved CT scanner service ~~and its unit(s)~~ is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(~~xiv~~V) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) An applicant approved under Section 4 shall not be required to be in compliance with subsection (c) but shall be in compliance with the following quality assurance standards:

(i) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month period after beginning operation of the dental CT scanner and annually thereafter.

(ii) The CT scanner will be used for the sole purpose of dental CT EXAMINATIONS~~images~~.

(iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT

EXAMINATIONS~~images~~ generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(~~v~~VI) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the dental CT EXAMINATIONS~~images~~ for performing dental procedures has had the appropriate training and/or experience certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(~~vi~~VII) The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan population, shall:

(a) not deny dental CT scanner services to any individual based on ability to pay or source of payment;

(b) provide dental ct scanning services to any individual based on the clinical indications of need for the service; and

(c) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(~~vii~~VIII) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site ~~or unit~~ as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~viii~~IX) Equipment to be replaced shall be removed from service.

(~~ix~~X) The applicant shall provide the Department with a notice stating the date the approved dental CT scanner service ~~and its unit(s)~~ is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(~~x~~XI) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~AGREED TO BY the applicant or its authorized agent.

(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) An applicant for a CT scanner used for dental research under Section 16~~1~~(1) shall agree that the services provided by the CT scanner approved pursuant to Section 16~~1~~(1) shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the CT scanner used for dental research pursuant to section 16~~1~~(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The CT scanner used for dental research approved pursuant to section 16~~1~~(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than section 16~~1~~.

(5) AN APPLICANT APPROVED UNDER SECTION 13 SHALL BE IN COMPLIANCE WITH THE FOLLOWING:

(A) THE APPLICANT AGREES TO PROVIDE QUARTERLY REPORTS TO THE DEPARTMENT

WITHIN ONE MONTH FOLLOWING THE END OF EACH CALENDAR QUARTER, STARTING WITH THE QUARTER THE APPLICANT INITIATES USE OF THE HOSPITAL-BASED PORTABLE CT SCANNER.

(B) THE DEPARTMENT WILL DEVELOP A QUESTIONNAIRE TO BE USED BY THE APPLICANT FOR THE QUARTERLY REPORT. THIS QUESTIONNAIRE, AT A MINIMUM, WILL INCLUDE INFORMATION REGARDING THE UTILIZATION, COST, AND BENEFIT FOR PATIENT CARE AS COMPARED TO THE USE OF FULL-BODY CT SCANNERS.

(C) THE DEPARTMENT WILL SUMMARIZE THE INFORMATION FROM THE QUARTERLY REPORTS AND PROVIDE AN ASSESSMENT TO THE COMMISSION PRIOR TO THE MARCH 2010 COMMISSION MEETING. THE COMMISSION MAY REQUEST UPDATES ON THE STATUS OF THE PILOT PROGRAM AT ITS DISCRETION.

Section 2014. Project delivery requirements - additional terms of approval for applicants involving mobile CT scanners

Sec. 2014. (1) In addition to the provisions of Section 193, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) A host facility shall submit only one CON application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community Health prior to ending service with an existing host facility.

(c) A CON shall be required to add a host facility.

(d) A CON shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner ~~equipment~~ as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner ~~unit~~ at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner ~~unit~~ of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT SCANNER services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the Department by the central service coordinator under the terms of Section 193(1)(c)(xi).

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the owner or the governing body of~~ AGREED TO BY the applicant or its authorized agent.

Section 215. Determination of CT Equivalents

Sec. 215. For purposes of these standards, CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

(D) THE CONVERSION FACTOR FOR PEDIATRIC/SPECIAL NEEDS PATIENTS DOES NOT APPLY TO PROCEDURES PERFORMED ON A DEDICATED PEDIATRIC CT SCANNER.

Table 1 Category	Number of Billable CT Procedures		Conversion Factor		CT Equivalents
Head Scans w/o Contrast	_____	X	1.00	=	_____
(includes dental CT EXAMINATIONS~~images~~)					
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS W/O CONTRAST (INCLUDES DENTAL CT EXAMINATIONS)		X	1.25	=	
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS WITH CONTRAST		X	1.50	=	
PEDIATRIC/SPECIAL NEEDS PATIENT HEAD SCANS W/O & W CONTRAST		X	2.00	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS W/O CONTRAST		X	1.75	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS WITH CONTRAST		X	2.00	=	
PEDIATRIC/SPECIAL NEEDS PATIENT BODY SCANS W/O & W CONTRAST		X	3.00	=	
TOTAL CT EQUIVALENTS					_____

Section 2216. Documentation of projections

Sec. 2216. ~~(1)~~ An applicant required to project volumes ~~of service~~ under sections 3, 4 and 5 shall DEMONSTRATE THE FOLLOWING, AS APPLICABLE:~~specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation the Department shall determine whether the projections are reasonable.~~

(1) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 3 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL PHYSICIAN REFERRALS THAT RESULTED IN AN ACTUAL SCAN FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION. HISTORICAL PHYSICIAN REFERRALS WILL BE VERIFIED WITH THE

DATA MAINTAINED BY THE DEPARTMENT THROUGH ITS "ANNUAL HOSPITAL STATISTICAL SURVEY" AND/OR "ANNUAL FREESTANDING STATISTICAL SURVEY."

(2) An applicant required to project ~~volumes of service~~ under Section 4 shall demonstrate that the projection is based on a combination of the following for the most recent 12-month period immediately preceding the date of the application:

(a) the number of dental procedures performed by the applicant, and

(b) the number of committed dental procedures performed by referring licensed dentists.

~~(3)~~ FURTHER, ~~T~~The applicant and the referring licensed dentists shall substantiate the numbers ~~in subsection (2)~~ through the submission of HIPAA compliant billing records.

(3) AN APPLICANT REQUIRED TO PROJECT UNDER SECTION 5 SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON HISTORICAL UTILIZATION AT THE APPLICANT'S SITE FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION.

(4) AN APPLICANT SHALL DEMONSTRATE THAT THE PROJECTED NUMBER OF REFERRALS TO BE PERFORMED AT THE PROPOSED SITE UNDER SUBSECTIONS (1) AND (2) ARE FROM AN EXISTING CT SCANNER SERVICE THAT IS IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE, AND WILL CONTINUE TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE SUBSEQUENT TO THE INITIATION OF THE PROPOSED CT SCANNER SERVICE BY AN APPLICANT. IN DEMONSTRATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICANT SHALL PROVIDE EACH OF THE FOLLOWING:

(A) A WRITTEN COMMITMENT FROM EACH REFERRING PHYSICIAN THAT HE OR SHE WILL REFER AT LEAST THE VOLUME OF CT SCANS TO BE TRANSFERRED TO THE PROPOSED CT SCANNER SERVICE FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE CT SCANNER SERVICE PROPOSED BY AN APPLICANT.

(B) THE NUMBER OF REFERRALS COMMITTED MUST HAVE RESULTED IN AN ACTUAL CT SCAN OF THE PATIENT AT THE EXISTING CT SCANNER SERVICE FROM WHICH REFERRAL WILL BE TRANSFERRED. THE COMMITTING PHYSICIAN MUST MAKE AVAILABLE HIPAA COMPLIANT AUDIT MATERIAL IF NEEDED UPON DEPARTMENT REQUEST TO VERIFY REFERRAL SOURCES AND OUTCOMES. COMMITMENTS MUST BE VERIFIED BY THE MOST RECENT DATA SET MAINTAINED BY THE DEPARTMENT THROUGH ITS "ANNUAL HOSPITAL STATISTICAL SURVEY" AND/OR "ANNUAL FREESTANDING STATISTICAL SURVEY."

(C) THE PROJECTED REFERRALS ARE FROM AN EXISTING CT SCANNER SERVICE WITHIN A 75-MILE RADIUS FOR RURAL AND MICROPOLITAN STATISTICAL AREA COUNTIES OR 20-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA COUNTIES.

Section 23~~17~~. Effect on prior CON review standards; comparative reviews

Sec. 23~~17~~. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~March 9, 2004~~SEPTEMBER 19, 2006 and effective ~~June 4, 2004~~DECEMBER 27, 2006.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS FOR CT SCANNER SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:
65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

Proton Beam Therapy Treatment

Marc Keshishian, MD

Chairperson

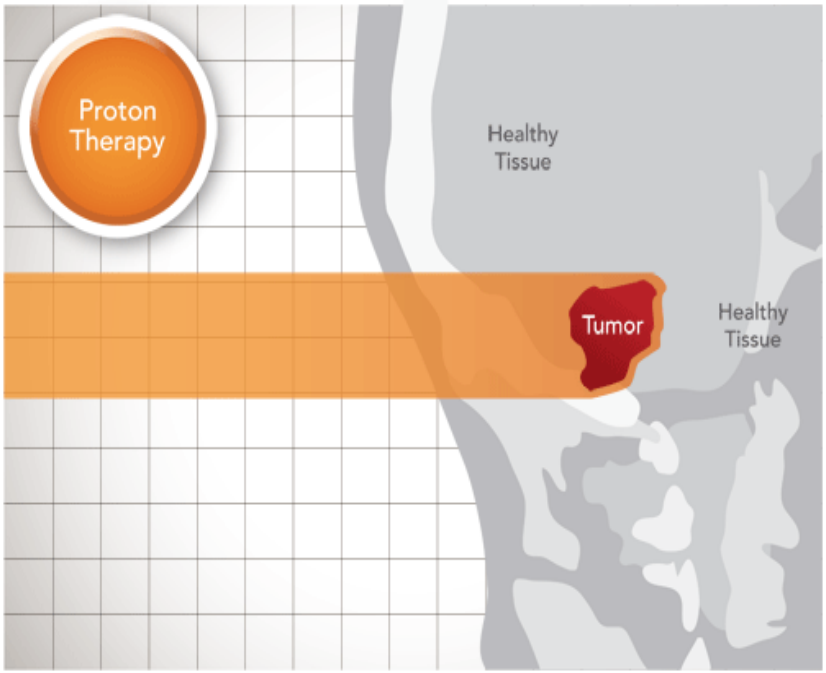
Workgroup

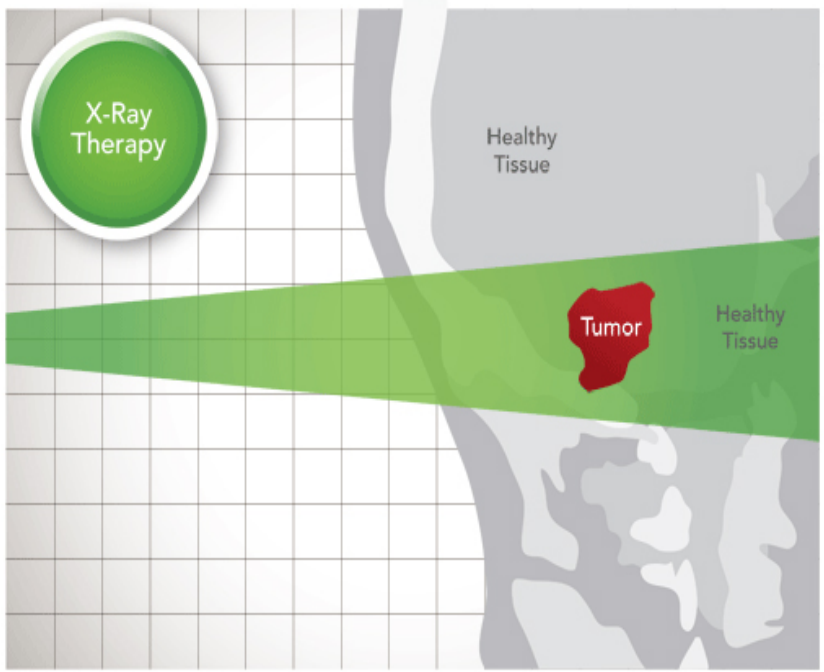
Proton Beam Therapy

Principles of Radiation Therapy

- Ionizing radiation causes tumor cell death
- Take advantage of differences between tumor cells and normal cells
- Normal tissues can be harmed by excess radiation

Proton vs X-ray (Photon) Therapy





- A lower dose of radiation is released at the surface, but a sharp burst of radiation is released as the proton beam reaches the tumor site.
- Proton radiation stops at the tumor, leaving the healthy cells beyond it unaffected.

- Radiation affects everything in its path so doctors often limit the dose to minimize damage to critical organs.
- X-rays continue to pass through the body after reaching the tumor, affecting the healthy cells beyond it.

Rationale Of Proton Beam Therapy (In Theory)

- Lower or No Risk of Additional Cancers
- Higher dosage
- Retreatments

How Many PBT Centers in Michigan?

- Use of proton therapy is projected[1] to grow 19% *annually* over the next decade
- Preliminary demand projections[2] indicate Michigan population would utilize 2-3 PBT Centers for *current* indications,[3] once technology becomes available (37% of RT for these conditions)
- Utilization could expand to 6-7 Centers once technology becomes available and *future* indications develop[4]
- Even if only half this demand materializes over the next 5 years, Michigan population would utilize 2-3 Centers with current indications, 3-4 as new indications develop

Notes: (1) Source: SG2
(2) As noted above, medical need for PBT is still being evaluated.
(3) Prostate, brain & CNS, eye cancer, arteriovenous malformation)
(4) (breast, lung, colo-rectal, head & neck, and liver)

Preliminary Market Analysis - Michigan

Indication	Cancer Incidence Rate (New Cases / 10,000 Pop)	Est. 2007 New Diagnoses	% Eligible for RT	# Patients Expected to Undergo RT	Potential Proton Therapy Penetration	Potential Proton Therapy Patients	Potential Demand for PBT Centers*
Current							
Prostate	8.1	8,200	59%	4,838	51%	2,467	
Brain & CNS	0.7	740	78%	577	52%	300	
Arteriovenous Malformation	0.1	100	18%	18	60%	11	
Intraocular Melanoma	0.1	100	20%	20	100%	20	
			Subtotal:	5,453		2,798	2-3
Future							
Breast	5.9	5,900	70%	4,130	9%	372	
Lung	8.2	8,210	64%	5,254	37%	1,944	
Colorectal	5.5	5,570	38%	2,117	58%	1,228	
Head & Neck	1.5	1,500	77%	1,155	29%	335	
Liver	0.6	580	40%	232	20%	46	
			Subtotal:	12,888		3,925	3-4
			Total:	18,341		6,723	6-7

***Assumes 1000 patients, ~30K fractions per PBT center per year (Breakeven is currently 600 patients per year)**

Sources: Morgan Stanley, U.S. Census Bureau; LEK Consultants; American Cancer Society; Michigan Dept of Community Health, BDC Advisors

What is the Evidence in Favor of Proton Therapy?

- Reviewed 36 published studies (only 2 phase III)
- Chordomas, ocular tumors, prostate, head and neck cancer

Brada, et al JCO 2007

Evidence Review

"…there are currently no studies demonstrating improved tumor control or survival in the treatment of localized prostate cancer with protons compared with best available photon RT. In addition, there is no clear evidence that high-dose proton boost is associated with less toxicity than the toxicity expected with photons."

Brada, et al JCO 2007

Cost

- An August 2007 article by Dr. Andre Konski looked at proton beam therapy versus IMRT for prostate cancer
  - Found proton beam therapy average cost was $58,610
  - Found IMRT average cost was $25,846[1]

1. Konski, A., Speier, et al. “Is Proton Beam Therapy Cost Effective in the Treatment of Adenocarcinoma of the Prostate?” Journal of Clinical Oncology. August 20, 2007 (25) 24: 3603-3608

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COMMENTS AND CONTROVERSIES

Should Randomized Clinical Trials Be Required for Proton Radiotherapy?

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James D. Cox, *Division of Radiation Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, TX*

Arguments for Protons

- **"Can anyone seriously believe that, if protons were cheaper that x-rays, there would be similar objections raised as to their immediate and widespread use?"**
- **"This seemingly rigorous academic discussion, in reality, is driven by the uncontested fact that protons are more expensive than x-rays."**
- **"Although we can understand (though not necessarily agree with) the desire to rely on phase III trials to establish the advantage of a superior therapy, we find it totally unacceptable to insist on what we judge to be unethical phase III trials purely to establish the financial cost-effectiveness of an admittedly better technology."**

H. Goiten: Harvard Medical School/J. Cox: M.D. Anderson Cancer Center

Overview of

- Currently, five operating proton therapy centers across the country
  - Linda Loma University Medical Center: California
  - Massachusetts General Hospital: Massachusetts
  - MD Anderson: Texas
  - Midwest Proton Radiotherapy Institute: Indiana
  - University of Florida: Florida
- Pending Facilities
  - University of Pennsylvania: Pennsylvania
  - Oklahoma ProCure Treatment Center: Oklahoma
  - Seattle Cancer Care Alliance: Washington
  - Hampton University: Virginia
  - Northern Illinois University: Illinois
  - Central DuPage Hospital: Illinois
  - University of Oklahoma Cancer Institute: Oklahoma
  - Barnes-Jewish Hospital: Missouri

Loma Linda University Medical Center

- First hospital based facility
- Opened in 1990
- Estimated cost of the facility $60 million
- Given a federal grant of approximately $20 million from the Department of Energy
- Privately financed the rest of the cost
- Medicare began covering treatment services right after the institute opened

Massachusetts General Hospital

- Harvard University's Cyclotron Laboratory treated more than nine thousand patients from 1961 to its closing in 2002
- Proton treatment transferred to main campus of MGH
- Facility begins operation in late 2001/early 2002
- Costs of the facility $46.1 million
- Jointly funded by MGH and the National Cancer Institute
- NCI provided $26.1 million for the project
- MGH provided funding for the rest of the project which included philanthropic support from individuals and foundations

Midwest Proton Radiotherapy Institute

- Treated first patient in 2004
- Built around an existing cyclotron owned by Indiana University
- Not attached to a hospital or university medical center; nearest hospital is 3 miles away
- Costs of the project $20 million
- Indiana State Legislature provides $10 million grant for the project
- Federal grants provided $4.5 million

MD Anderson Proton Therapy Center

- Began operation in 2006
- Total cost of project was $125 million
- For-profit independent center, less than a mile from the nearest hospital
- MD Anderson provided the lease for the land valued at $2.5 million
- Investment bank Sanders Morris Harris and healthcare facility developer the Styles Company raised the capital for the project
- Investors include pension funds, international health care companies, and private investors

University of Florida

- Began operation in 2006
- Estimated cost between $110-$125 million
- Attached to University of Florida and Shands Medical Center
- State provided $11 million grant
- Jacksonville Economic Development Commission provided $80 million
- Private donations contributed a small amount

University of Pennsylvania

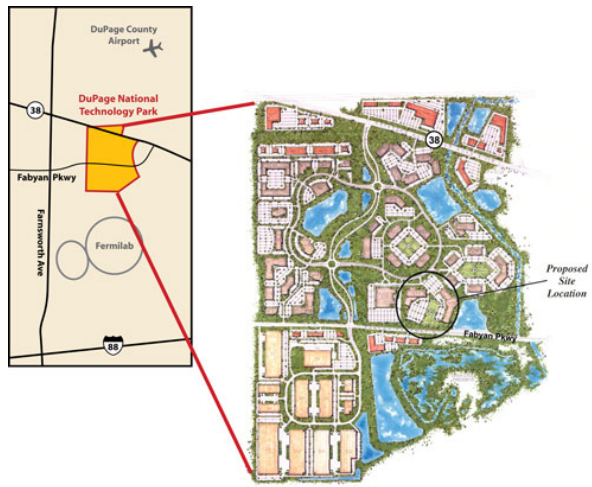
- Estimated completion 2009
- Estimated cost $140 million
- Will be part of the Perelman Center for Advanced Medicine, a large outpatient facility adjacent to the Hospital of the University of Pennsylvania
- Ralph Roberts and son Brian L. Roberts, founder and CEO of Comcast, provided $15 million donation
- Department of Defense is providing substantial funding
- Penn Medicine and Children's Hospital will cover the remaining cost

Oklahoma ProCure Treatment Center

- Estimated completion 2009
- Private practice proton treatment center, about 2 miles from the nearest hospital
- Estimated cost $95 million
- Partnership of ProCure Proton Centers, Inc. and Radiation Oncology Associates and Radiation Medicine Associates
- Privately financed

Northern Illinois University

- Expected completion 2010
- Estimated cost $160 million
- Proposed location in West Chicago
- North of Fermi National Lab, little over 5 miles from the nearest hospital
- Currently has received $7.3 million in federal funding
- Illinois Health Facilities Planning granted a certificate of exemption after NIU argued the facility is not a health-care facility under state law



Central DuPage Hospital: Illinois

- Expected completion 2010
- Estimated cost $125 million
- Construction and financing done through ProCure Treatment Centers, Inc.
- Tentatively planned to be attached to CDH
- Completely privately financed
- Proposed location in close vicinity to the NIU site
- Applying for a full certificate of need, Illinois Health Facilities Planning Board will consider the application at their April meeting

Seattle Cancer Care Alliance

- Estimated date of completion 2010-2011
- Estimated cost $100 million
- Will be part of Northwest Hospital's campus
- Received $2.1 million in federal funds
- Equity investors
- SCCA will invest between $10-$20 million of its own money for the project

Hampton University

- Estimated completion 2010-2011
- Estimated cost $225 million
- Will be the largest proton independent treatment facility in the world
- Will be located about 3 miles from the nearest hospital
- Received $1 million from the state of Virginia
- Seeking federal funding
- Majority of cost will be privately financed

Barnes-Jewish Hospital

- Approved by CON of Missouri
- Waiting for the approval of a smaller cyclotron unit developed by Still Rivers Systems
- Estimated cost $20 million
- The miniature cyclotron has yet to be approved by the FDA
- Will be based within in a single hospital room

University of Oklahoma

- Signed agreement to buy the small unit cyclotron from Still Rivers System
- Estimated cost $20 million
- Proposed site for the cancer treatment center will be within blocks of Oklahoma Procure Treatment Center
- Will be part of the OU Cancer Institute, less than a mile from the main OU Medical Center Campus

Conclusions

- Proton therapy has hypothetical advantages over photon therapy
- Presently, it would be used for prostate cancer
- Absolutely no evidence that proton therapy provides superior outcomes to photon therapy except in a few rare pediatric cancers
- Medicare pays more than twice as much for proton therapy as photon therapy

Recommendations

- A consortium composed of Michigan hospitals should bring proton beam therapy to Michigan
- This consortium should have hospitals from at least four HSA
- All hospitals that have more than 30,000 ETV should be part of the consortium
  - Reason for 30,000 ETV is to ensure they have staff that have the expertise in radiation oncology
  - Ensure that hospitals are invited (an inclusive process)
  - Not too many hospitals that make the consortium unwielding

Recommendations (cont.)

- The consortium should attempt to enroll patients into clinical protocols so science can be advanced
- As more new expensive technology becomes available, a consortium can be a model for making new technology available in a cost effective manner

"Proton and other particle therapies need to be explored as potentially more effective and less toxic RT techniques. A passionate belief in the superiority of particle therapy and commercially driven acquisition and running of proton centers provide little confidence that appropriate information will be become available. Objective outcome data from prospective studies is only likely to come from fully supported academic activity away from commercial influence. An uncontrolled expansion of clinical units offering as yet unproven and expensive proton therapy is unlikely to advance the field of radiation oncology or be of benefit to cancer patients."

Brada, et al JCO 2007

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code that involve MRT services/units.

(2) An MRT service/unit is a covered clinical service for purposes of Part 222 of the Code. An MRT service/unit previously approved pursuant to Section 7 of these standards now seeking approval to operate pursuant to sections 4, 5, 6, 8, 9, or 10 shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of an MRT service/unit. An MRT unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of a non-special MRT service/unit.

(3) The Department shall use sections 4, 5, 6, 8, 9, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 15, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 11 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) ~~As used in~~FOR PURPOSES OF these standards:

(a) "Acquisition of an existing MRT service or existing MRT unit(s)" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or existing MRT unit(s).

(b) "Begin operation of an MRT service" means the establishment of a non-special MRT unit at a geographic location where an MRT service is not currently provided. The term does not include the acquisition or relocation of an existing MRT service and/or unit(s) or the renewal of a lease.

(c) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, and Iridium-192.

(d) "Cancer treatment program" means a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability, and, either on-site or through written agreements with other providers, all of the following services: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) MRT capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.

(e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan compiled Laws.

(g) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(h) "Computer based treatment planning system" means a computer system capable of displaying radiation doses and dose distributions within a patient using anatomical data from that patient and using measured radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a brachytherapy package.

(i) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(j) "Cyber knife" means~~, for purposes of these standards,~~ a treatment device that is a frameless special stereotactic radiosurgery unit that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment and use this information to target the radiation beam emitted by the linear accelerator.

(K) "CYCLOTRON" MEANS, FOR PURPOSES OF SECTION 10, A PARTICLE ACCELERATOR IN WHICH HYDROGEN PARTICLES ARE ACCELERATED AND PROTONS ARE EXTRACTED TO CREATE A PROTON BEAM.

(L~~k~~) "Department" means the Michigan Department of Community Health (MDCH).

(M~~l~~) "Dosimetrist" means a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(N~~m~~) "Driving miles" means the number of miles from the address of the proposed MRT service to the address of the closest existing MRT unit. Driving miles is the number of miles from address to address as identified by use of mapping software that is verifiable by the Department.

(O~~n~~) "Duplication factor" means the number derived by subtracting the duplication rate from 1.

(P~~o~~) "Duplication rate" means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.

(Q~~p~~) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit, that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit. Section 12 sets forth how ETVs shall be calculated.

(R~~q~~) "Existing MRT service" means a CON approved and operational facility and equipment used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all existing MRT units at a geographic location(s).

(S~~r~~) "Existing MRT unit" means a CON approved and operational equipment used to provide MRT services.

(T~~s~~) "Expand an existing MRT service" means adding one additional MRT unit to the number of existing MRT units.

(U~~t~~) "Full time equivalent" or "FTE" means an individual(s) with normally scheduled working hours of 40 hours per week.

(V~~u~~) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(W~~v~~) "Geographic location" means either (i) the geographic location of a licensed health facility as defined in the CON Review Standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location.

(X~~w~~) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, or heavy ions with masses greater than that of an electron.

(Y~~x~~) "Image guided radiation therapy" or "IGRT" means the use of in-room imaging to allow precise target localization using ultrasound, implanted fiducial markers or image reconstruction using kV or megavoltage beams. Two-dimensional port films using patient anatomy for localization do not constitute IGRT.

(Z~~y~~) "Immediately available" means continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.

(AA~~z~~) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(BB~~aa~~) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(CC~~bb~~) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(DD~~cc~~) "Institutional review board" or "IRB" means an institutional review board, as defined by Public Law 93-348, that is regulated by Title 45 CFR 46.

(EE~~dd~~) “Isocenter” means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(FF~~ee~~) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the hospital 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 site as authorized by licensure.

(GG~~ff~~) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission (NRC) or registered by the Michigan Department of Community Health, Division of Health Facilities and Services, Radiation Safety Section.

(HH~~gg~~) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(II~~hh~~) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board certified or board qualified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics.

(JJ~~ii~~) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by a MRT unit.

(KK~~jj~~) "MRT program" means one or more MRT services operated at one or more geographic locations under the same administrative unit.

(LL~~kk~~) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(MM~~ll~~) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(NN~~mm~~) "Metropolitan statistical area county” means a county located in a metropolitan statistical area as that term is defined under the “standards for defining metropolitan and micropolitan statistical areas” by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(OO~~nn~~) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department, Vital Records and Health Data Development Section, mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(PP~~oo~~) "Micropolitan statistical area county” means a county located in a micropolitan statistical area as that term is defined under the “standards for defining metropolitan and micropolitan statistical areas” by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(QQpp) "Multi-disciplinary cancer committee" means a standing committee that (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation; (ii) meets at least on a quarterly basis; and (iii) is responsible for (a) establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility; (b) monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and (c) oversight of the applicant's tumor registry for quality control, staging, and abstracting.

(RRqq) "New cancer case," ~~for purposes of these standards,~~ means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.

(SSrr) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit OR A PROTON BEAM THERAPY UNIT.

(TTss) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(UUtt) "Patient care evaluation studies" means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; hospital wide quality assurance activities; and ongoing monitoring, evaluating, and action planning.

(VVuu) "Planning area" means the groups of counties shown in Section 16.

(WW) "PROTON BEAM THERAPY" OR "PBT" MEANS A TYPE OF PARTICLE THERAPY THAT UTILIZES A CYCLOTRON TO ACCELERATE PROTONS, SENDING THEM THROUGH A BEAM TRANSPORT SYSTEM TO INDIVIDUAL TREATMENT ROOM(S), WHERE THEY ARE USED TO IRRADIATE A TUMOR SITE IN THE TREATMENT OF CANCER.

(XXvv) "Relocation of an existing MRT service and/or MRT unit(s)" means a change in the geographic location within the same planning area.

(YYww) "Replace/upgrade an existing MRT unit" means 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.

(ZZxx) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R., p. 82238 (December 27, 2000) and as shown in Appendix C.

(AAAyy) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(BBBzz) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(CCCaaa) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) heavy particle accelerator, (ii) gamma knife, (iii) dedicated stereotactic radiosurgery unit, (iv) dedicated total body irradiator (TBI), (v) an OR-based IORT unit, or (vi) cyber knife.

(DDDbbb) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the destruction of a precisely defined intracranial and/or extracranial tumor or lesion.

(EEEccc) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

(FFFddd) "Treatment site" means the anatomical location of the MRT treatment.

(GGGeee) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(HHHfff) "Tumor registry," ~~for the purposes of these standards,~~ means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

(Illggg) "Very complex treatment visit" means those visits listed in Section 12 that involve special techniques in the performance of the MRT.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Modification of the Appendices

Sec. 3. (1) The Commission may modify the Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program presented to the Commission by the Department.

(2) The Commission may periodically modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data provided by MRT providers as part of a Department survey presented to the Commission by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) Modifications made by the Commission pursuant to subsections (1) or (2) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 4. Requirements for approval - applicants proposing to begin operation of a MRT service OTHER THAN AN MRT SERVICE PROVIDING PBT

Sec. 4. (1) An applicant proposing to begin operation of a MRT service shall demonstrate that:
(a) a minimum of 8,000 equivalent treatment visits (ETVs) for each proposed unit results from application of the methodology described in Section 11, and
(b) the proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.
(b) The site of the proposed MRT service is 60 driving miles or more from the nearest MRT service.
(c) The proposed MRT service projects a minimum of 5,500 equivalent treatment visits (ETVs) for each proposed unit based on the application of the methodology described in Section 11.
(d) The proposed MRT unit is not a special purpose MRT unit.

(3) All applicants under this section shall demonstrate, at the time the application is submitted to the Department, that the following staff, at a minimum, will be provided:
(a) 1 FTE board-certified or board-qualified physician trained in radiation oncology,
(b) 1 board-certified or board-qualified radiation physicist certified in therapeutic radiologic physics,
(c) 1 dosimetrist or physics assistant,
(d) 2 radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)], and
(e) 1 program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (3)(a).

Section 5. Requirements for approval - applicants proposing to expand an existing MRT service

Sec. 5. (1) An applicant proposing to expand an existing MRT service with an additional non-special MRT unit shall demonstrate:

(a) an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units, and

(b) the additional unit shall be located at the same site, unless the requirements of section 9(2) also have been met.

(2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate each of the following, as applicable:

(a) 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.

(b) An applicant proposing to expand by adding a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(c) An applicant proposing to expand by adding a heavy particle accelerator shall have available, either on-site or through written agreement(s), 3-dimensional imaging and 3-dimensional treatment planning capabilities. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

(d) An applicant proposing to expand by adding and operating a dedicated stereotactic radiosurgery unit (including a gamma knife and cyber knife) shall demonstrate that (i) the applicant has, at the time the application is filed, a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.

(e) An applicant proposing to expand by adding an operating room based intraoperative MRT unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.

Section 6. Requirements for approval - applicants proposing to replace/upgrade an existing MRT unit(s)

Sec. 6. An applicant requesting to replace/upgrade an existing MRT unit(s) shall demonstrate each of the following, as applicable.

(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only unit at that geographic location, shall demonstrate each of the following:

(a) The unit performed at least 5,500 ETVs in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service which is the only MRT service in the planning area shall demonstrate each of the following:

(a) Each unit at the geographic location of the unit to be replaced operated at an average of at least 5,500 ETVs in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:

(a) Each non-special unit at the geographic location of the unit to be replaced operated at a total of at least 13,000 ETVs for two units and an additional 5,500 ETVs for each additional unit (i.e., 13,000 ETVs + 5,500 ETVs = 18,500 ETVs for three units, 13,000 ETVs + 5,500 etvs + 5,500 ETVs = 24,000 ETVs for four units, etc.) in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(4) An applicant requesting to replace/upgrade an existing special purpose unit shall demonstrate each of the following, as applicable:

(a) The special purpose unit to be replaced operated at the following level of utilization during the most recent 12-month period, as applicable:

(i) an average of 7,000 ETVs for each heavy particle accelerator;

(ii) an average of 1,000 ETVs for each OR-based IORT unit, gamma knife, cyber knife, dedicated stereotactic radiosurgery unit, or dedicated total body irradiator.

(b) The replacement special purpose unit will be located at the same geographic location as the special purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements of sections 5 and 9 have been met.

(c) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program.

(5) An applicant under this section shall demonstrate that the MRT unit proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles; that the existing unit clearly poses a threat to the safety of the public; or that the proposed replacement unit offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

(6) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.

Section 7. Requirements for approval - applicants proposing to use MRT units exclusively for research

Sec. 7. (1) An applicant proposing a MRT unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(b) The MRT unit shall operate under a protocol approved by the applicant's IRB.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 15(1)(c)(v), (viii), (xiii); 15(2); 15(3); and 15(4).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 4, 5; 6; and 15(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of these standards.

(3) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.

Section 8. Requirements for approval - applicants proposing to acquire an existing MRT service or an existing MRT unit(s)

Sec. 8. (1) An applicant proposing to acquire an existing MRT service and its MRT unit(s) shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing MRT service and its MRT unit(s).

(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.
(c) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.

(2) An applicant proposing to acquire an existing MRT unit(s) of an existing MRT service shall demonstrate that it meets all of the following:
(a) The project is limited solely to the acquisition of an existing MRT unit(s) of an existing MRT service.
(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.
(c) The project will not result in the replacement/upgrade of an existing MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.
(d) The requirements of Section 4(3) have been met.

Section 9. Requirements for approval - applicants proposing to relocate an existing MRT service and/or MRT unit(s)

Sec. 9. (1) An applicant proposing to relocate an existing MRT service and its MRT unit(s) shall demonstrate that it meets all of the following:
(a) The relocation of the existing MRT service and its MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.
(b) The new geographic location will be in the same planning area as the existing geographic location.
(c) The project will not result in the replacement/upgrade of the existing MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.
(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(2) An applicant proposing to relocate an MRT unit(s) of an existing MRT service shall demonstrate that it meets all of the following:
(a) The relocation of the MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.
(b) The new geographic location will be in the same planning area as the existing geographic location.
(c) The project will not result in the replacement/upgrade of the existing MRT (unit)s to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.
(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.
(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.
(f) For a micropolitan statistical area or rural county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 5,500 ETVs in the most recent 12-month period. For a metropolitan statistical area county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 8,000 ETVs in the most recent 12-month period.
(g) The requirements of Section 4(3) have been met.
(h) A special purpose unit cannot be relocated to a site that does not have an existing non-special purpose unit.

SECTION 10. REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PBT

SEC. 10. (1) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PBT SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

(A) AN APPLICANT SHALL BE A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN MICHIGAN.

(B) AN APPLICANT SHALL BE A STATEWIDE COLLABORATIVE THAT CONSISTS OF, AT A MINIMUM:

(I) ALL MICHIGAN HOSPITAL OWNED MRT SERVICES WITH MORE THAN 30,000 ETVS, WHICH INCLUDES

(II) THE HIGHEST VOLUME HOSPITAL OWNED MRT SERVICES FROM AT LEAST FOUR OF THE EIGHT MICHIGAN PLANNING AREAS.

(C) FOR THE PURPOSES OF THIS SECTION, ETVS SHALL BE THOSE FROM THE MOST RECENT DATA AVAILABLE TO THE DEPARTMENT AT THE TIME THE APPLICATION IS SUBMITTED.

(D) AN APPLICANT SHALL PROVIDE DOCUMENTATION OF ITS PROCESS, POLICY AND PROCEDURES THAT WILL ALLOW ANY OTHER INTERESTED ENTITIES TO PARTICIPATE IN THE STATEWIDE COLLABORATIVE AND THE PBT SERVICES IT OFFERS.

(E) AN APPLICANT SHALL PROVIDE AN IMPLEMENTATION PLAN FOR FINANCING AND OPERATING THE PROPOSED PBT SERVICE INCLUDING, BUT NOT LIMITED TO, HOW PHYSICIAN STAFF PRIVILEGES, PATIENT REVIEW, PATIENT SELECTION, AND PATIENT CARE MANAGEMENT SHALL BE DETERMINED.

(F) AN APPLICANT SHALL INDICATE THAT PBT SERVICES WILL BE PROVIDED TO BOTH ADULT AND PEDIATRIC PATIENTS.

(G) AN APPLICANT SHALL DEMONSTRATE THAT THE PBT SERVICE WILL HAVE SIMULATION CAPABILITIES AVAILABLE FOR USE IN TREATMENT PLANNING.

(2) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PBT SHALL BE EXEMPT FROM MEETING THE REQUIREMENTS OF SECTIONS 5; 6; 8; AND 9 OF THESE STANDARDS.

Section 11~~10~~. Requirements for approval -- all applicants

Sec. 11~~0~~. ~~An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or 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.~~AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY 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.

Section 12~~1~~. Methodology for computing the projected number of equivalent treatment visits

Sec. 12~~1~~. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).

(1) Identify the number of new cancer cases documented in accord with the requirements of Section 14.

(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.

(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.

(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.

(5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.

(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.

(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.

(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.

(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5) by 2.5.

(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of estimated ETVs.

Section 132. Equivalent treatment visits

Sec. 132. For purposes of these standards, equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable section(s) of these standards, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding ETV weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) The number of ETVs for each category determined pursuant to subsection (2) shall be summed to determine the total ETVs for the time period specified in the applicable section(s) of these standards.

TABLE 1
Equivalent TreatmentS

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.50	
Very Complex:		
Total Body Irradiation		5.00
Hemi Body Irradiation		4.00
Heavy Particle Accelerator		5.00
Stereotactic radio-surgery/radio-therapy*		8.00
(non-gamma knife and cyber knife**)		
Gamma Knife**		8.00
Dedicated OR-Based IORT		20.00

All patients under 5 years of age receive a 2.00 additive factor.

*After the first visit, each additional visit receives 2.5 additional ETVs with a maximum of five visits per course of therapy.

**After the first isocenter, each additional isocenter receives 4 additional ETVs.

Section 143. Commitment of new cancer cases

Sec. 143. (1) An applicant proposing to use new cancer cases shall demonstrate all of the following:

(a) Each entity contributing new cancer case data provides, as part of the application at the time it is submitted to the Department, 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.

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

(2) An entity currently operating or approved to operate a MRT service shall not contribute new cancer cases to initiate any MRT service.

Section 154. Documentation of new cancer case data

Sec. 154. (1) An applicant required to document volumes of new cancer cases shall submit, as part of its application, documentation from the Department, Vital Records and Health Data Development Section, verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available from the State Registrar.

(2) New cancer case data supporting an application under these standards shall be submitted to the Michigan Cancer Surveillance Program using a format and media specified in instructions from the State Registrar.

Section 165. Project delivery requirements terms of approval for all applicants

Sec. 165. (1) An applicant shall agree that, if approved, MRT services shall be delivered in compliance with the following applicable terms of CON approval for each geographical location where the applicant operates an MRT unit:

(a) Compliance with these standards.
(b) Compliance with applicable safety and operating standards.
(c) Compliance with the following quality assurance standards:

(i)(A) The non-special MRT units and heavy particle accelerators approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(B) The non-special MRT units and heavy particle accelerators approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(ii) An applicant shall establish a mechanism to assure that (a) the MRT service is staffed so that the MRT unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapy technologist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the department may accept other evidence that the applicant has established and operates a satisfactory quality assurance mechanism to assure that the MRT unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.

(iii) At a minimum, the following staff shall be provided: (a) 1 FTE board-certified or board- qualified physician trained in radiation oncology for each 250 patients treated with MRT annually, (b) 1 board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation, (c) 1 dosimetrist or physics assistant for every 300 patients treated with MRT annually, (d) 2 FTE radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)] for every MRT unit per shift of operation (not including supervisory time), and (e) 1 FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(iv) All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be IMMEDIATELY AVAILABLE~~on site at the geographic location of the unit~~ during the operation of the unit(s).

(v) The applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. MRT facility staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site in or immediately available to the MRT unit at all times when patients are treated.

(vi) An applicant shall operate a cancer treatment program. For purposes of evaluating this subsection, the department shall consider it prima facie evidence of meeting this requirement if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. However, the applicant may submit and the Department may accept other evidence that the applicant operates a cancer treatment program as defined in these standards.

(vii) A MRT service will have simulation capability at the same geographic location of the MRT service/unit.

(viii) An applicant shall participate in the Michigan Cancer Surveillance Program.

(ix) An applicant required to document new cancer cases shall agree to pay the State Registrar's costs for verification of the new cancer case data.

(x) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.

(xi) The applicant, to assure that the MRT unit will be utilized by all segments of the Michigan population, shall: (a) not deny MRT services to any individual based on ability to pay or source of payment, (b) provide MRT services to an individual based on the clinical indications of need for the service, and (c) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xii)(A) The applicant shall participate in a data collection network established and administered by the department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department or its designee, and approved by the CON Commission. The applicant shall provide the required data on a separate basis for each separate and distinct geographic location or unit, and separately for non-special MRT units and each type of special purpose MRT unit, as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(B) If the applicant intends to include research treatment visits conducted by a MRT unit other than an MRT unit approved exclusively for research pursuant to Section 7 in its utilization statistics, the applicant shall submit to the department a copy of the research protocol with evidence of approval by the IRB. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall not report to the Department any treatment visits conducted by an MRT unit approved pursuant to Section 7.

(xiii) The applicant shall provide the Department with a notice stating the first date on which the MRT service and its unit(s) became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved and to seek approval under a separate CON application to operate the unit as a non-special MRT unit.

(xv) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification as a total body irradiator. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, OR PBT UNIT, shall meet any requirements specified by the Department, Division of Health Facilities and Services, Radiation Safety Section.

(xvi) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) An applicant for an MRT unit under Section 7 shall agree that the services provided by the MRT unit approved pursuant to Section 7 shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the research use of the MRT unit approved pursuant to Section 7 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRT unit approved pursuant to Section 7 shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRT unit pursuant to Part 222 and these standards, other than Section 7.

(3) AN APPLICANT FOR AN MRT SERVICE PROVIDING PBT UNDER SECTION 10 SHALL AGREE THAT THE PBT SERVICE APPROVED PURSUANT TO SECTION 10 SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING ADDITIONAL TERMS OF CON APPROVAL:

(A) ALL PATIENTS TREATED AT THE APPROVED PBT SERVICE SHALL BE EVALUATED FOR POTENTIAL ENROLLMENT IN RESEARCH STUDIES FOCUSING ON THE APPLICABILITY AND

EFFICACY OF USING PROTON BEAM THERAPY TO TREAT SITE SPECIFIC CANCER TUMORS. THESE REPORTS SHALL BE SHARED WITH THE CON COMMISSION.

(B) THE PBT SERVICE SHALL PROVIDE THE CON COMMISSION, ON AN ANNUAL BASIS, WITH REPORTS DESIGNED TO ASSESS THE AFFORDABLITY, QUALITY, AND ACCESSIBILITY OF PBT SERVICES IN MICHIGAN.

(C) AN APPLICANT SHALL BE REQUIRED TO REPORT TO THE DEPARTMENT, ON AN ANNUAL BASIS, VOLUME RELATED DATA FOR ITS PBT UNIT.

(D) THE APPLICANT SHALL BE REQUIRED TO MEET THE MINIMUM VOLUME REQUIREMENTS FOR PBT AS ESTABLISHED BY THE CON COMMISSION IN ANY SUBSEQUENT REVISION OF THE CON STANDARDS FOR AN MRT SERVICE.

(43) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(54) The applicable agreements and assurances required by this section shall be in the form of a certification ~~authorized by the owner or governing body of~~AGREED TO BY the applicant or its authorized agent.

Section 176. Planning areas

Sec. 176. Counties assigned to each planning area are as follows:

PLANNING AREA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford

8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 18~~7~~. Effect on prior CON review standards; comparative reviews

Sec. 18~~7~~. (1) These CON review standards supersede and replace the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units approved by the CON Commission on ~~March 14, 2000~~DECEMBER 13, 2005 and effective ~~April 28, 2000~~JANUARY 20, 2006.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

DUPLICATION RATES AND FACTORS

The following Duplication Rates and Factors are effective December 11, 2007 and remain in effect until otherwise changed by the Commission.

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.21085	0.78915
2	0.23517	0.76483
3	0.11219	0.88781
4	0.25664	0.74336
5	0.21849	0.78151
6	0.34615	0.65385
7	0.21865	0.78135
8	0.12314	0.87686

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective December 11, 2007 and remains in effect until otherwise changed by the Commission.

Treatment Visit Category	Statewide Percent
Simple	1.6%
Intermediate	.8%
Complex	73.4%
IMRT	24.2%

Source: 2006 Annual Hospital Statistical Survey

APPENDIX C

CON REVIEW STANDARDS FOR MRT SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information And Regulatory Affairs
United States Office of Management And Budget

Comments to the Certificate of Need Commission Regarding Proton Beam Therapy

Benjamin Movsas, MD

Good Afternoon. My name is Benjamin Movsas and I am Chairman of Radiation Oncology for Henry Ford Hospital and Health Network. Henry Ford Health System provides radiation oncology services at five locations in southeast Michigan, at which, during 2006, we provided more than 87,000 Equivalent Treatment Visits to patients from all over Michigan.

I recently have participated as a member of the Commission's MRT workgroup chaired by Commissioner Keshishian. The first issue that the workgroup addressed was whether there was a need for proton beam therapy in the State of Michigan. The general consensus was that the availability of this service within the state could be of benefit to Michigan citizens.

Next, the workgroup had substantial discussion regarding the types of cases that could be more beneficially treated with protons, as opposed to currently available radiation therapy using photons. In this regard, however, a similar consensus was not achieved. Several participants, myself included, feel that the benefit for protons exists currently only for selected conditions, such as pediatric tumors. While treatment of some other cancers holds some promise, it has not been clearly demonstrated using evidence based medicine that there is substantial incremental benefit in the treatment of prostate or many other adult tumors.

While Michigan citizens deserve the full benefit of proven treatments for their illnesses, one must be certain that the benefits are clearly demonstrated, particularly when the investment is as large as this one. Indeed, as Chair of the Quality of Life committee for the national Radiation Therapy Oncology Group, I feel strongly that quality of life should be carefully studied prospectively in patients receiving protons in order to document its potential clinical benefit.

Interestingly, claims have been made that one benefit of proton therapy is that it can be used to treat recurrent cancer, while standard radiation, (i.e., with photons), cannot. However, this is simply not the case. It is important to recognize that over the last several years the tools that we have available to treat our patients with photons have improved immensely with respect to their precision. For example, over the last few years, at Henry Ford Hospital, we have helped to pioneer and have published our experience with a cutting edge technique using photons, called stereotactic spine radiosurgery, that affords millimeter accuracy to safely and effectively re-treat recurrent tumors that are in close proximity to the spinal cord.

Given the enormous capital investment needed to initiate this service, I support the notion that entry into this field must be cautious and must be done on a collaborative basis with a consortium of providers. This approach was suggested by the Commission at the January meeting and we agree that it has great merit. Such an approach would spread the financial risk and allow providers to learn from each other regarding the clinical usefulness of this therapy for patients.

Moreover, although it has been suggested that physicians from throughout the state could send their patients to a facility that is developed by a single provider, the opportunity for collegial participation in the development of clinical protocols, patient selection criteria and ongoing clinical research on the efficacy of this treatment would not be supported under that scenario.

It has also been suggested that developing a consortium of providers to offer this service would slow down the process. Given the size of the investment and the need to develop a service that will be successful well into the future, it seems that "getting it right" is more important than "getting it fast."

Furthermore, providing this service under any model that does not include a collaborative effort by multiple providers invites the prospect of more of these units in the state than the need in the population would justify. Indeed, it is

distressing to learn that plans are currently underway for two proton facilities in the Chicago suburbs which will only be several miles apart. We believe that by requiring that a proton facility here be through a consortium of providers, the State of Michigan can lead the country by developing a paradigm for such large healthcare projects to be done properly -- in a manner that is reasonable, safe, cost efficient, and that involves a fully collaborative approach based on a foundation of active clinical trials.

On behalf of the Henry Ford Health System I appreciate the opportunity to make these comments. We strongly believe that the citizens of Michigan would best be served if protons were offered to them through a consortium of providers, pulling together the wide range of talent and expertise across our State in the fields of radiation oncology, biology and physics. It is our recommendation that the Commission accept the language that has been approved by the overwhelming majority of the workgroup members and that the process of changing the standards to incorporate this language begin today.

I would be glad to respond to any questions you might have. Thank you.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve nursing homes and hospital long-term-care units.

(2) A nursing home licensed under Part 217 and a hospital long-term-care unit (HLTCU) defined in Section 20106(6) are covered health facilities for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 12, 13, and 14 of these standards, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

~~(4) The Department shall use Section 7 of these standards, as applicable, in applying Section 22225(2)(a)(iii) of the Code, being Section 333.22225(2)(a)(iii) of the Michigan Compiled Laws.~~

(~~5~~4) The Department shall use Section 11 of these standards, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(~~6~~5) The Department shall use Section 10(2) of these standards, as applicable, in applying Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of ~~a new~~ AN EXISTING nursing home ~~or~~ /HLTCU" means the issuance of a new nursing home/HLTCU ~~(including HLTCU)~~ license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed AND OPERATING nursing home/ HLTCU ~~(including HLTCU)~~ and which does not involve a change in bed capacity of that health facility.

(b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. For planning areas with an ADC of less than 100, the ADC adjustment factor is 0.90 and for planning areas with an ADC of 100 or more, the ADC adjustment factor is 0.95.

(c) "Applicant's cash" means the total ~~of the following items~~ UNRESTRICTED CASH, DESIGNATED FUNDS, AND RESTRICTED FUNDS reported by the applicant AS THE SOURCE OF FUNDS IN THE APPLICATION. ~~on the "Source of Funds" form (form number T-150-G-11.04, or any subsequent replacement form): (i) unrestricted cash; (ii) designated funds; (iii) restricted funds; (iv) planned gifts, bequests, donations, and pledges; and (v) interest income during construction.~~

~~(d) "Average total proposed project cost per bed" or "A" is calculated by the Department by summing the "Total proposed project cost" of each qualifying project, and then dividing the sum by the total number of beds proposed by those qualifying projects. The total number of beds shall include new, replacement, and converted beds.~~

(eD) "Base year" means 1987 or the most recent year for which verifiable data collected as part of the Michigan Department of Community Health Annual Survey of Long-Term-Care Facilities or other comparable MDCH survey instrument are available.

(fE) "Certificate of Need Commission" or "Commission" means the commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(gF) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(G) "COMMON OWNERSHIP OR CONTROL" MEANS A NURSING HOME, REGARDLESS OF THE STATE IN WHICH IT IS LOCATED, THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT NURSING HOME PURSUANT TO THE DEFINITION OF COMMON OWNERSHIP OR CONTROL UTILIZED BY THE DEPARTMENT'S BUREAU OF HEALTH SYSTEMS.

(h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area OR STATEWIDE SPECIAL POOL GROUP and which are being reviewed comparatively in ~~accord~~ ACCORDANCE with the CON rules.

(i) "Converted ~~bed/~~space" means~~, for purposes of these standards, an~~ existing ~~bed or~~ space in a health facility that is not currently licensed as PART OF THE ~~a~~ nursing home/HLTCU ~~bed~~ and is proposed to be licensed as ~~a~~ nursing home or HLTCU ~~bed~~ SPACE. An example is proposing to license ~~a~~ home for the aged ~~bed~~ SPACE as ~~a~~ nursing home ~~bed~~ SPACE.

(j) "Department" means the Michigan Department of Community Health (MDCH).

(k) "Department inventory of beds" means the current list, for each planning area maintained on a continuing basis by the Department: (i) licensed nursing home beds ~~(including MR and MI beds)~~ and (ii) nursing home beds approved by a valid CON issued under ~~either former Part 221 or~~ Part 222 of the Code which are not yet licensed. It does not include (a) nursing home beds approved from the statewide pool and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws.

(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds ~~(including MR and MI beds)~~, (ii) nursing home beds approved by a valid CON issued under ~~either former Part 221 or~~ Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under ~~former Part 221 or~~ Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code ~~(other than the application or applications in the comparative group under review)~~ which is pending final Department decision. ~~The following exceptions to this definition exist: (a) the 174 licensed beds at the Pinecrest Medical Care Facility geographically located in Menominee County will be allocated to three planning areas as follows: 68 beds in the Menominee planning area, 53 beds in the Delta planning area, and 53 beds in the Dickinson planning area;~~ (bA) nursing home beds approved from the statewide pool are excluded; and (cB) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

~~(m) "Gross square feet" means the area of the building as measured by the outside building walls.~~

(nM) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in Section 14.

(oN) "Hospital long-term-care unit" or "HLTCU" means a nursing care facility, owned and operated by and as part of a hospital, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(O) "LICENSED ONLY FACILITY" MEANS A LICENSED NURSING HOME THAT IS NOT CERTIFIED FOR MEDICARE OR MEDICAID.

(p) "Licensed site" means ~~either (i) in the case of a single site hospital or nursing home,~~ the location of the health facility authorized by license and listed on that licensee's certificate of licensure ~~or (ii) in the case of a hospital or nursing home with multiple sites, the location of each separate and distinct health facility as authorized by licensure~~.

(q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

~~(r) "Medicaid eligible recipient" means a patient deemed eligible by the Michigan Department of Community Health, or its designated agent, to receive Medicaid reimbursement from the time of admission to a nursing home/HLTCU.~~

(~~s~~R) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

~~(t) "MI beds" means nursing home beds in a nursing home licensed by the Department for the care of mentally ill patients.~~

(~~u~~S) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

~~(v) "MR beds" means nursing home beds in a nursing home licensed by the Department for the care of mentally retarded patients.~~

~~(w) "Net usable area" means the usable floor area of a patient sleeping room excluding any vestibules (including door swings), toilet rooms, and built-in closets.~~

(T) "NEW DESIGN MODEL" MEANS A NURSING HOME/HLTCU BUILT IN ACCORDANCE WITH SPECIFIED DESIGN REQUIREMENTS AS IDENTIFED IN THE APPLICABLE SECTIONS.

(~~x~~U) "Nonrenewal or revocation of license for cause" means that the Department did not renew or revoked the nursing home's/HLTCU's license based on the nursing home's/HLTCU's failure to comply with state licensing standards.

(~~y~~V) "Nonrenewal or termination of certification for cause" means the nursing home/HLTCU Medicare and/or Medicaid certification was terminated or not renewed based on the nursing home's/HLTCU's failure to comply with Medicare and/or Medicaid participation requirements.

(~~z~~W) "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. THIS TERM APPLIES TO THE LICENSEE ONLY AND NOT THE REAL PROPERTY OWNER IF DIFFERENT THAN THE LICENSEE.

(~~aa~~X) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.

(~~bb~~Y) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be calculated using verifiable data from either (i) the actual number of patient days of care for 12 continuous months of data from the MDCH Annual Survey of Long-Term-Care Facilities or other comparable MDCH survey instrument or (ii) the actual number of patient days of care for 4 continuous quarters of data as reported to the Department for purposes of compiling the "Staffing/Bed Utilization Ratios Report," whichever is the most recent available data.

(~~cc~~Z) "Planning area" means the geographic boundaries of each county in Michigan with the exception of: (i) Houghton and Keweenaw counties, which are combined to form one planning area and (ii) Wayne County which is divided into three planning areas. Section ~~13~~ 12 identifies the three planning areas in Wayne County and the specific geographic area included in each.

(~~dd~~AA) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, established by the CON Commission for which nursing home bed needs are developed. The planning year shall be a year for which official population projections, from the Department of Management and Budget or U.S. Census, data are available.

(~~ee~~BB) "Physically conforming beds," for purposes of Section 10(3), means beds which meet the maximum occupancy and minimum square footage requirements as specified in Section 483.70(d)(1) of the Code of Federal Regulations for Medicare certification (42 CFR) or any federal regulations for Medicare certification addressing maximum occupancy and minimum square footage requirements approved subsequent to the effective date of these standards.

(~~ff~~CC) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards.

~~(gg) "Readmission" means the admission of a patient following a temporary absence from the same nursing home/HLTCU during which time the bed was held open or the patient had the option to return to the next available bed at the same nursing home/HLTCU.~~

(DD) "RELOCATION OF EXISTING NURSING HOME/HLTCU BEDS" MEANS A CHANGE IN THE LOCATION OF EXISTING NURSING HOME/HLTCU BEDS FROM THE LICENSED SITE TO A DIFFERENT LICENSED SITE WITHIN THE PLANNING AREA.

(EE) "RENEWAL OF LEASE" MEANS EXECUTION OF A LEASE BETWEEN THE LICENSEE AND A REAL PROPERTY OWNER IN WHICH THE TOTAL LEASE COSTS EXCEED THE CAPITAL EXPENDITURE THRESHOLD.

(~~hh~~FF) "Replacement bed" means a CHANGE IN THE LOCATION OF THE LICENSED NURSING HOME/HLTCU, THE REPLACEMENT OF A PORTION OF THE LICENSED BEDS AT THE SAME LICENSED SITE, OR THE REPLACEMENT OF A PORTION OF THE LICENSED BEDS PURSUANT TO THE NEW MODEL DESIGN. ~~nursing home bed with a valid license that meets all of the following conditions: (i) an equal or greater number of nursing home beds are currently licensed to the applicant at the licensed site at which the beds proposed for replacement are currently licensed, (ii) the nursing home beds are proposed for replacement~~ THE NURSING HOME/HLTCU BEDS WILL BE in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) WITHIN THE REPLACEMENT ZONE. ~~, and (iii) the nursing home beds to be replaced will be located in the replacement zone.~~

(~~ii~~GG) "Replacement zone" means a proposed licensed site that is,

(i) for a rural or micropolitan statistical area county, within the same planning area as the existing licensed site.

(ii) for a county that is not a rural or micropolitan statistical area county,

(A) within the same planning area as the existing licensed site and

(B) within a three-mile radius of the existing licensed site.

~~(jj) "Room plan changes" means any construction activities in patient rooms, including bathroom areas, which involve moving walls. This does not include cosmetic renovations such as wallpaper, painting, carpeting, or other activities associated with normal wear and tear.~~

(~~kk~~HH) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(~~ll~~II) "Staffing/Bed Utilization Ratios Report" means the report issued by the Department on a quarterly basis.

~~(mm) "Total proposed project cost" means the total of all the items listed on the applicant's "Project Cost" form (form number T-150-G-11.02 or any subsequent replacement form) excluding the item "Pre-existing debt to be refinanced." For projects where existing beds/space are being converted to nursing home/HLTCU beds and the number of square feet of facility space to be allocated to the nursing~~

~~home/HLTCU will increase, the imputed costs of the beds/space to be converted shall be determined based on a fair market value appraisal of the tangible assets to be converted. The imputed costs for the beds/space to be converted shall be entered on the "Project Cost" form on the line for "Construction Costs: Other."~~

~~(nn) "Total proposed project cost per bed" is determined by dividing the applicant's "Total proposed project cost" by the applicant's proposed number of beds. The total proposed number of beds shall include new, replacement, and converted beds.~~

(~~oo~~JJ) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per 1,000 population during a one-year period.

~~(pp) "Vestibule" means a small entrance hall or passageway, between a common corridor and a patient room, of sufficient width and length to allow a corridor entrance door to swing in without obstruction. A vestibule also may provide an adequate area to permit an attached toilet room door sufficient clear swing space so as not to impact on minimum patient room net usable area requirements.~~

(2) The definitions in Part 222 of the Code shall apply to these standards.

Section 3. Determination of needed nursing home bed supply

Sec. 3 (1)(a) The age specific use rates for the planning year shall be the actual statewide age specific nursing home use rates using data from the base year.

(b) The age cohorts for each planning area shall be: (i) age 0 - 64 years, (ii) age 65 - 74 years, (iii) age 75 - 84 years, and (iv) age 85 and older.

(c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the use rates for the base year for each corresponding age cohort, established in accord with subsection (1)(b), are set forth in Appendix A.

(2) The number of nursing home beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area in the age cohorts established in subsection (1)(b).

(b) Multiply each population age cohort by the corresponding use rate established in Appendix A.

(c) Sum the patient days resulting from the calculations performed in subsection (b). The resultant figure is the total patient days.

(d) Divide the total patient days obtained in subsection (c) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).

(e) The following shall be known as the ADC adjustment factor. (i) If the ADC determined in subsection (d) is less than 100, divide the ADC by 0.90. (ii) If the ADC determined in subsection (d) is 100 or greater, divide the ADC by 0.95.

(f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.

Section 4. Bed need

Sec. 4. (1) ~~For purposes of these standards, until otherwise changed by the Commission, the~~ THE bed need numbers shown in Appendix B and incorporated as part of these standards shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

(2) ~~The Commission may direct the~~ THE Department SHALL ~~to~~ apply the bed need methodology in Section 3 ON A BIENNIAL BASIS.

(3) ~~The Commission shall designate the~~ THE base year and the planning year that shall be utilized

in applying the methodology pursuant to subsection (2) SHALL BE SET ACCORDING TO THE MOST RECENT DATA AVAILABLE TO THE DEPARTMENT.

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

(5) New bed need numbers established by subsections (2) and (3) shall supersede the bed need numbers shown in Appendix B and shall be included as an amended appendix to these standards.

(6) Modifications made by the Commission pursuant to this section shall not require ~~ad hoc~~ STANDARD advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the age specific use rates by changing the base year.

Sec. 5. (1) The ~~Commission may modify the~~ base year SHALL BE MODIFIED based on data obtained from the ~~Michigan~~ Department ~~of Community Health Annual Survey of Long-Term-Care Facilities or other comparable MDCH survey instrument~~ AND presented to the Commission ~~by the Department~~. The Department shall calculate use rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates based on ~~1989~~ 2006 information, or the most recent base year information available biennially after ~~1989~~ 2006, to the CON Commission.

(2) The Commission shall establish the effective date of the modifications made pursuant to subsection (1).

(3) Modifications made by the Commission pursuant to subsection (1) shall not require ~~ad hoc~~ STANDARD advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 6. Requirements for approval ~~- applicants proposing~~ to increase beds in a planning area ~~or replace beds outside a replacement zone~~

Sec. 6. ~~(a)~~ An applicant proposing to increase the number of nursing home beds in a planning area must MEET ~~demonstrate~~ THE FOLLOWING AS APPLICABLE: ~~the proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in Appendix B. An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area set forth in Appendix B, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.~~

(1) AN APPLICANT PROPOSING TO INCREASE THE NUMBER OF NURSING HOME BEDS IN A PLANNING AREA BY BEGINNING OPERATION OF A NEW NURSING HOME/HLTCU OR INCREASING THE NUMBER OF BEDS TO AN EXISTING LICENSED NURSING HOME/HLTCU SHALL DEMONSTRATE THE FOLLOWING:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN	ALL MICHIGAN NURSING HOMES/HLTCUS

NURSING HOMES/HLTCUS	UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(B)THE APPLICANT CERTIFIES THAT THE REQUIREMENTS FOUND IN THE MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES OF MICHIGAN, REFERENCED IN SECTION 20145 (6) OF THE PUBLIC HEALTH CODE, ACT 368 OF 1978, AS AMENDED AND ARE PUBLISHED BY THE DEPARTMENT, WILL BE MET WHEN THE ARCHITECTUAL BLUEPRINTS ARE SUBMITTED FOR REVIEW AND APPROVAL BY THE DEPARTMENT.

(C) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

~~(b) An applicant proposing to replace existing licensed nursing home beds in the same planning area, but outside the replacement zone, must demonstrate each of the following: (i) the total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply set forth in Appendix B and (ii) the number of beds to be replaced is equal to or less than the number of currently licensed beds at the health facility at which the beds proposed for replacement are currently located. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.~~

(D) THE PROPOSED INCREASE, IF APPROVED, WILL NOT RESULT IN THE TOTAL NUMBER OF EXISTING NURSING HOME BEDS IN THAT PLANNING AREA EXCEEDING THE NEEDED

NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B, UNLESS ONE OF THE FOLLOWING IS MET:

(I) AN APPLICANT MAY REQUEST AND BE APPROVED FOR UP TO A MAXIMUM OF 20 BEDS IF, WHEN THE TOTAL NUMBER OF "EXISTING NURSING HOME BEDS" IS SUBTRACTED FROM THE BED NEED FOR THE PLANNING AREA SET FORTH IN APPENDIX B, THE DIFFERENCE IS EQUAL TO OR MORE THAN 1 AND EQUAL TO OR LESS THAN 20. THIS SUBSECTION IS NOT APPLICABLE TO PROJECTS SEEKING APPROVAL FOR BEDS FROM THE STATEWIDE POOL OF BEDS.

(~~c~~II) An exception to the number of beds ~~that~~ may be approved, ~~pursuant to subsection (a) or (b) shall be made if the requirements set forth in both (i~~A) ~~and (ii~~B) ~~are met~~ IF THE APPLICANT FACILITY HAS EXPERIENCED AN AVERAGE OCCUPANCY RATE OF 97% FOR 12 QUARTERS BASED ON THE DEPARTMENT'S "STAFFING/BED UTILIZATION RATIOS REPORT." The number of beds that may be approved in excess of the bed need for each planning area identified in Appendix B is set forth in subsection (~~iii~~CA).

~~(i~~A) ~~The applicant requesting additional nursing home/HLTCU beds has experienced an occupancy rate, at the nursing home/HLTCU at which the additional beds are proposed, of at least 97% for each of the 12 most recent continuous quarters for which verifiable data are available to the Department on its "Staffing/Bed Utilization Ratios Report."~~

~~(ii~~B) ~~The occupancy rate for all nursing homes/HLTCUs in the planning area, including nursing home beds approved from the statewide pool, has been at least 97% for each of the 12 most recent continuous quarters for which verifiable data are available to the Department on its "Staffing/Bed Utilization Ratios Report."~~

(~~iii~~CA) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the occupancy rate for the planning area in which the additional beds are proposed to the ADC adjustment factor for that planning area as shown in Appendix B. The number of beds shall be calculated by (1) dividing the actual number of patient days of care provided during the most recent 12-month period for which verifiable data are available to the Department provided by all nursing home (including HLTCU) beds in the planning area, including patient days of care provided in beds approved from the statewide pool of beds and dividing that result by 365 (or 366 for leap years); (2) dividing the result of step (1) by the ADC adjustment factor for the planning area in which the beds are proposed to be added; (3) rounding the result of step (2) up to the next whole number; and (4) subtracting the total number of beds in the planning area including beds approved from the statewide pool of beds from the result of step (3). If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is equal to or more than 20, the number of beds that may be approved pursuant to this subsection shall be up to that number of beds. If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is less than 20, the number of additional beds that may be approved shall be that number of beds or up to a maximum of 20 beds.

(III) AN APPLICANT MAY REQUEST AND BE APPROVED FOR UP TO A MAXIMUM OF 20 BEDS IF THE FOLLOWING REQUIREMENTS ARE MET:

(A) THE PLANNING AREA IN WHICH THE BEDS WILL BE LOCATED SHALL HAVE A POPULATION DENSITY OF LESS THAN 28 INDIVIDUALS PER SQUARE MILE BASED ON THE 2000 U.S. CENSUS FIGURES AS SET FORTH IN APPENDIX D.

(B) THE APPLICANT FACILITY HAS EXPERIENCED AN AVERAGE OCCUPANCY RATE OF 92% FOR THE MOST RECENT 24 MONTHS BASED ON THE DEPARTMENT'S "STAFFING/BED UTILIZATION RATIOS REPORT."

(2) AN APPLICANT PROPOSING TO INCREASE THE NUMBER OF NURSING HOME BEDS IN A PLANNING AREA BY BEGINNING OPERATION OF A NEW NURSING HOME/HLTCU OR INCREASING THE NUMBER OF BEDS TO AN EXISTING LICENSED NURSING HOME/HLTCU PURSUANT TO THE NEW DESIGN MODEL SHALL DEMONSTRATE THE FOLLOWING:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL

PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(B) THE PROPOSED PROJECT RESULTS IN NO MORE THAN 100 BEDS PER NEW DESIGN MODEL AND MEETS THE FOLLOWING DESIGN STANDARDS:

(I) FOR INPATIENT FACILITIES THAT ARE NOT LIMITED TO GROUP RESIDENT HOUSING OF 10 BEDS OR LESS, THE CONSTRUCTION STANDARDS SHALL BE THOSE APPLICABLE TO NURSING HOMES IN THE DOCUMENT ENTITLED MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES IN MICHIGAN AND INCORPORATED BY REFERENCE IN SECTION 20145(6) OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20145(6) OF THE MICHIGAN COMPILED LAWS OR ANY FUTURE VERSIONS.

(II) FOR SMALL RESIDENT HOUSING UNITS OF 10 BEDS OR LESS THAT ARE SUPPORTED BY A CENTRAL SUPPORT INPATIENT FACILITY, THE CONSTRUCTION STANDARDS SHALL BE THOSE APPLICABLE TO HOSPICE RESIDENCES PROVIDING AN INPATIENT LEVEL OF CARE, EXCEPT THAT:

(A) AT LEAST 100% OF ALL RESIDENT SLEEPING ROOMS SHALL MEET BARRIER FREE REQUIREMENTS;

(B) ELECTRONIC NURSE CALL SYSTEMS SHALL BE REQUIRED IN ALL FACILITIES;
(C) HANDRAILS SHALL BE REQUIRED ON BOTH SIDES OF PATIENT CORRIDORS; AND
(D) CEILING HEIGHTS SHALL BE A MINIMUM OF 7 FEET 10 INCHES.
(III) THE PROPOSED PROJECT SHALL COMPLY WITH APPLICABLE LIFE SAFETY CODE REQUIREMENTS AND SHALL BE FULLY SPRINKLED AND AIR CONDITIONED.
(IV) THE DEPARTMENT MAY WAIVE CONSTRUCTION REQUIREMENTS FOR NEW DESIGN MODEL PROJECTS IF AUTHORIZED BY LAW.
(C) THE PROPOSED PROJECT SHALL INCLUDE AT LEAST 80% ~~OF THE BEDS IN~~ SINGLE OCCUPANCY RESIDENT ROOMS WITH AN ADJOINING BATHROOM SERVING NO MORE THAN TWO RESIDENTS IN BOTH THE CENTRAL SUPPORT INPATIENT FACILITY AND ANY SUPPORTED SMALL RESIDENT HOUSING UNITS.
(D) THE PROPOSED INCREASE, IF APPROVED, WILL NOT RESULT IN THE TOTAL NUMBER OF EXISTING NURSING HOME BEDS IN THAT PLANNING AREA EXCEEDING THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B, UNLESS THE FOLLOWING IS MET:
(I) AN APPROVED PROJECT INVOLVES REPLACEMENT OF A PORTION OF THE BEDS OF AN EXISTING FACILITY AT A GEOGRAPHIC LOCATION WITHIN THE REPLACEMENT ZONE THAT IS NOT PHYSICALLY CONNECTED TO THE CURRENT LICENSED SITE. IF A PORTION OF THE BEDS ARE REPLACED AT A LOCATION THAT IS NOT THE CURRENT LICENSED SITE, A SEPARATE LICENSE SHALL BE ISSUED TO THE FACILITY AT THE NEW LOCATION.
(E) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

~~**Section 7. Requirements for projects involving new construction or renovation**~~

~~Sec. 7. (1) For projects involving new construction or renovation, an applicant shall demonstrate each of the following, as applicable:~~
~~(a) For projects involving the new construction of patient rooms, or room plan changes, the patient rooms shall be constructed or renovated to be consistent with the following minimum square feet of net usable area:~~

~~Room Type~~	~~Net Usable Area Minimum Sq. Ft.~~
~~One person~~	~~100~~
~~Two person~~	~~160~~
~~Three person~~	~~240~~
~~Four person~~	~~320~~

~~(b) For proposed projects involving construction of an entire facility (whether new or replacement), the proposed total gross square footage of the facility shall be no less than 200 gross square feet per bed.~~

~~(2) An applicant proposing a project involving new construction or renovation shall demonstrate that a plan of correction for cited code deficiencies including life and fire safety (if any) for the applicant health facility has been submitted to and approved by the Department of Consumer and Industry Services, Division of Licensing and Certification.~~

SECTION 7. REQUIREMENTS FOR APPROVAL TO RELOCATE EXISTING NURSING HOME/HLTCU BEDS

SEC. 7. (1) AN APPLICANT PROPOSING TO RELOCATE EXISTING NURSING HOME/HLTCU BEDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B, IF THE APPLICANT DEMONSTRATES ALL OF THE

FOLLOWING:

(A) AN EXISTING NURSING HOME/HLTCU MAY RELOCATE NO MORE THAN 50% OF ITS BEDS TO ANOTHER EXISTING NURSING HOME/HLTCU.

(B) THE NURSING HOME/HLTCU FROM WHICH THE BEDS ARE BEING RELOCATED AND THE NURSING HOME/HLTCU RECEIVING THE BEDS, SHALL NOT REQUIRE ANY OWNERSHIP RELATIONSHIP.

(C) THE NURSING HOME/HLTCU FROM WHICH THE BEDS ARE BEING RELOCATED AND THE NURSING HOME/HLTCU RECEIVING THE BEDS MUST BE LOCATED IN THE SAME PLANNING AREA.

(D) THE NURSING HOME/HLTCU FROM WHICH THE BEDS ARE BEING RELOCATED HAS NOT RELOCATED ANY BEDS WITHIN THE LAST SEVEN (7) YEARS.

(E) THE RELOCATED BEDS SHALL BE LICENSED TO THE RECEIVING NURSING HOME/HLTCU AND WILL BE COUNTED IN THE INVENTORY FOR THE APPLICABLE PLANNING AREA.

(F) AT THE TIME OF TRANSFER TO THE RECEIVING FACILITY, PATIENTS IN BEDS TO BE RELOCATED MUST BE GIVEN THE CHOICE OF REMAINING IN ANOTHER BED IN THE NURSING HOME/HLTCU FROM WHICH THE BEDS ARE BEING TRANSFERRED OR TO THE RECEIVING NURSING HOME/HLTCU. PATIENTS SHALL NOT BE INVOLUNTARY DISCHARGED TO CREATE A VACANT BED.

(2) AN APPLICANT PROPOSING TO ADD NEW NURSING HOME/HLTCU BEDS, AS THE RECEIVING EXISTING NURSING HOME/HLTCU UNDER SUBSECTION (1), SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B, IF THE APPLICANT DEMONSTRATES ALL OF THE FOLLOWING:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE

CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(~~A~~B) THE APPROVAL OF THE PROPOSED NEW NURSING HOME/HLTCU BEDS SHALL NOT RESULT IN AN INCREASE IN THE NUMBER OF NURSING HOME BEDS IN THE PLANNING AREA.

(~~B~~C) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

Section 8. Requirements for approval ~~-- replacement beds~~ TO REPLACE BEDS

Sec. 8. An applicant proposing ~~replacement beds~~ TO REPLACE BEDS MUST MEET THE FOLLOWING AS APPLICABLE.

(1) AN APPLICANT PROPOSING TO REPLACE BEDS WITHIN THE REPLACEMENT ZONE shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B if the applicant demonstrates all of the following:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF

OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

~~(a) the project proposes to replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently located;,~~

(B) THE PROPOSED PROJECT IS EITHER TO REPLACE THE LICENSED NURSING HOME/HLTCU TO A NEW SITE OR REPLACE A PORTION OF THE LICENSED BEDS AT THE EXISTING LICENSED SITE.

(~~b~~C) the proposed ~~licensed~~ site is ~~in~~ WITHIN the replacement zone~~,~~. ~~and~~

~~(c) the applicant meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.~~

(D) THE APPLICANT CERTIFIES THAT THE REQUIREMENTS FOUND IN THE MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES OF MICHIGAN, REFERENCED IN SECTION 20145 (6) OF THE PUBLIC HEALTH CODE, ACT 368 OF 1978, AS AMENDED AND ARE PUBLISHED BY THE DEPARTMENT, WILL BE MET WHEN THE ARCHITECTUAL BLUEPRINTS ARE SUBMITTED FOR REVIEW AND APPROVAL BY THE DEPARTMENT.

(E)A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

~~(F)THE HLTCU REMAINS WITHIN THE HOSPITAL IF THE PROJECT INVOLVES AN HLTCU.~~

(2) AN APPLICANT PROPOSING TO REPLACE A LICENSED NURSING HOME/HLTCU OUTSIDE THE REPLACEMENT ZONE SHALL DEMONSTRATES ALL OF THE FOLLOWING:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED

LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(B) THE TOTAL NUMBER OF EXISTING NURSING HOME BEDS IN THAT PLANNING AREA IS EQUAL TO OR LESS THAN THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B.

(C) THE NUMBER OF BEDS TO BE REPLACED IS EQUAL TO OR LESS THAN THE NUMBER OF CURRENTLY LICENSED BEDS AT THE NURSING HOME/HLTCU AT WHICH THE BEDS PROPOSED FOR REPLACEMENT ARE CURRENTLY LOCATED.

(D) THE APPLICANT CERTIFIES THAT THE REQUIREMENTS FOUND IN THE MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES OF MICHIGAN, REFERENCED IN SECTION 20145 (6) OF THE PUBLIC HEALTH CODE, ACT 368 OF 1978, AS AMENDED AND ARE PUBLISHED BY THE DEPARTMENT, WILL BE MET WHEN THE ARCHITECTUAL BLUEPRINTS ARE SUBMITTED FOR REVIEW AND APPROVAL BY THE DEPARTMENT.

(E)A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

~~(F)THE HLTCU REMAINS WITHIN THE HOSPITAL IF THE PROJECT INVOLVES AN HLTCU.~~

(3) AN APPLICANT PROPOSING TO REPLACE BEDS WITH A NEW DESIGN MODEL SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B IF THE APPLICANT DEMONSTRATES ALL OF THE FOLLOWING:

(A) THE PROPOSED PROJECT RESULTS IN NO MORE THAN 100 BEDS PER NEW DESIGN MODEL AND MEETS THE FOLLOWING DESIGN STANDARDS:

(I) FOR INPATIENT FACILITIES THAT ARE NOT LIMITED TO GROUP RESIDENT HOUSING OF 10 BEDS OR LESS, THE CONSTRUCTION STANDARDS SHALL BE THOSE APPLICABLE TO NURSING HOMES IN THE DOCUMENT ENTITLED MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES IN MICHIGAN AND INCORPORATED BY REFERENCE IN SECTION 20145(6) OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20145(6) OF THE MICHIGAN COMPILED LAWS OR ANY FUTURE VERSIONS.

(II) FOR SMALL RESIDENT HOUSING UNITS OF 10 BEDS OR LESS THAT ARE SUPPORTED BY A CENTRAL SUPPORT INPATIENT FACILITY, THE CONSTRUCTION STANDARDS SHALL BE THOSE APPLICABLE TO HOSPICE RESIDENCES PROVIDING AN INPATIENT LEVEL OF CARE, EXCEPT THAT:

(A) AT LEAST 100% OF ALL RESIDENT SLEEPING ROOMS SHALL MEET BARRIER FREE REQUIREMENTS;

(B) ELECTRONIC NURSE CALL SYSTEMS SHALL BE REQUIRED IN ALL FACILITIES;

(C) HANDRAILS SHALL BE REQUIRED ON BOTH SIDES OF PATIENT CORRIDORS; AND

(D) CEILING HEIGHTS SHALL BE A MINIMUM OF 7 FEET 10 INCHES.

(III) THE PROPSED PROJECT SHALL COMPLY WITH APPLICABLE LIFE SAFETY CODE REQUIREMENTS AND SHALL BE FULLY SPRINKLED AND AIR CONDITIONED.

(IV) THE DEPARTMENT MAY WAIVE CONSTRUCTION REQUIREMENTS FOR NEW DESIGN MODEL PROJECTS IF AUTHORIZED BY LAW.

(B) THE PROPOSED PROJECT SHALL INCLUDE AT LEAST 80% ~~OF THE BEDS IN~~ SINGLE OCCUPANCY RESIDENT ROOMS WITH AN ADJOINING BATHROOM SERVING NO MORE THAN TWO RESIDENTS IN BOTH THE CENTRAL SUPPORT INPATIENT FACILITY AND ANY SUPPORTED SMALL RESIDENT HOUSING UNITS. IF THE PROPOSED PROJECT IS FOR REPLACEMENT/RENOVATION OF AN EXISTING FACILITY AND UTILIZES ONLY A PORTION OF ITS CURRENTLY LICENSED BEDS, THE REMAINING ROOMS AT THE EXISTING FACILITY SHALL NOT EXCEED DOUBLE OCCUPANCY.

(C) THE PROPOSED PROJECT SHALL BE WITHIN THE REPLACEMENT ZONE UNLESS THE APPLICANT DEMONSTRATES ALL OF THE FOLLOWING:

(I) THE PROPOSED SITE FOR THE REPLACEMENT BEDS IS IN THE SAME PLANNING AREA, AND NOT WITHIN A THREE MILE RADIUS OF A LICENSED NURSING HOME THAT HAS BEEN NEWLY CONSTRUCTED, OR REPLACED (INCLUDING APPROVED PROJECTS) WITHIN FIVE CALENDAR YEARS PRIOR TO THE DATE OF THE APPLICATION,

(II) THE APPLICANT SHALL PROVIDE A SIGNED AFFIDAVIT OR RESOLUTION FROM ITS GOVERNING BODY OR AUTHORIZED AGENT STATING THAT THE PROPOSED LICENSED SITE WILL CONTINUE TO PROVIDE SERVICE TO THE SAME MARKET, AND

(III) THE CURRENT PATIENTS OF THE FACILITY/BEDS BEING REPLACED SHALL BE ADMITTED TO THE REPLACEMENT BEDS WHEN THE REPLACEMENT BEDS ARE LICENSED, TO THE EXTENT THAT THOSE PATIENTS DESIRE TO TRANSFER TO THE REPLACEMENT FACILITY/BEDS.

(D) AN APPROVED PROJECT MAY INVOLVE REPLACEMENT OF A PORTION OF THE BEDS OF AN EXISTING FACILITY AT A GEOGRAPHIC LOCATION WITHIN THE REPLACEMENT ZONE THAT IS NOT PHYSICALLY CONNECTED TO THE CURRENT LICENSED SITE. IF A PORTION OF THE BEDS ARE REPLACED AT A LOCATION THAT IS NOT THE CURRENT LICENSED SITE, A SEPARATE LICENSE SHALL BE ISSUED TO THE FACILITY AT THE NEW LOCATION.

(E) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

Section 9. Requirements for approval ~~– acquisition of a new~~ TO ACQUIRE AN EXISTING NURSING HOME/HLTCU OR RENEW THE LEASE OF AN EXISTING nursing home ~~or /~~HLTCU

Sec. 9. AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING NURSING HOME/HLTCU OR RENEW THE LEASE OF AN EXISTING NURSING HOME/HLTCU MUST MEET THE FOLLOWING AS APPLICABLE:

(1) An applicant proposing to acquire ~~a new~~AN EXISTING nursing home ~~or /~~HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home or HLTCU ~~subject to the proposed acquisition~~ is located if the

applicant demonstrates ~~that~~ all of the following ~~are met~~:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(~~a~~B) the acquisition will not result in a change in bed capacity,

(~~b~~C) the licensed site does not change as a result of the acquisition, ~~and~~

(~~c~~D) the project is limited solely to the acquisition of a nursing home ~~or~~ /HLTCU with a valid license.

(E)A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT, AND

~~(F) THE HLTCU REMAINS WITHIN THE HOSPITAL, IF THE PROJECT INVOLVES AN HLTCU.~~

(~~G~~F) THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, SUCH AS MY INNERVIEW, ADVANCING EXCELLENCE, OR ANOTHER COMPARABLE PROGRAM FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE

OMBUDSMAN, BUREAU OF HEALTH SYSTEMS, AND SHALL POST THE ANNUAL REPORT IN THE FACILITY IF THE FACILITY BEING ACQUIRED HAS MET ANY OF CONDITIONS IN SUBSECTIONS (A)(I), (II), (III), (IV), (V), OR (VI).

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING NURSING HOME/HLTCU APPROVED PURSUANT TO THE NEW DESIGN MODEL SHALL DEMONSTRATE THE FOLLOWING:

(A) AT THE TIME OF APPLICATION, THE APPLICANT, AS IDENTIFIED IN THE TABLE, SHALL PROVIDE A REPORT DEMONSTRATING THAT IT DOES NOT MEET ANY OF THE FOLLOWING CONDITIONS IN 14%, BUT NOT MORE THAN FIVE, OF ITS NURSING HOMES/HLTCUS:

TYPE OF APPLICANT	REPORTING REQUIREMENT
APPLICANT WITH ONLY MICHIGAN NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH 10 OR MORE MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL
APPLICANT WITH FEWER THAN 10 MICHIGAN NURSING HOMES/HLTCUS AND OUT OF STATE NURSING HOMES/HLTCUS	ALL MICHIGAN AND OUT OF STATE NURSING HOMES/HLTCUS UNDER COMMON OWNERSHIP OR CONTROL

(I) A STATE ENFORCEMENT ACTION RESULTING IN A LICENSE REVOCATION, REDUCED LICENSE CAPACITY, OR RECEIVERSHIP WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(II) A FILING FOR BANKRUPTCY WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(III) TERMINATION OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT INITIATED BY THE DEPARTMENT OR LICENSING AND CERTIFICATION AGENCY IN ANOTHER STATE, WITHIN THE LAST THREE YEARS, OR FROM THE CHANGE OF OWNERSHIP DATE IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION.

(IV) A NUMBER OF CITATIONS AT LEVEL D OR ABOVE, EXCLUDING LIFE SAFETY CODE CITATIONS, ON THE SCOPE AND SEVERITY GRID ON TWO CONSECUTIVE STANDARD SURVEYS THAT EXCEEDS TWICE THE STATEWIDE AVERAGE, CALCULATED FROM THE QUARTER IN WHICH THE STANDARD SURVEY WAS COMPLETED, IN THE STATE IN WHICH THE NURSING HOME/HLTCU IS LOCATED. FOR LICENSED ONLY FACILITIES, A NUMBER OF CITATIONS AT TWO TIMES THE AVERAGE OF ALL LICENSED ONLY FACILITIES ON THE LAST TWO LICENSING SURVEYS. HOWEVER, IF THE FACILITY HAS COME UNDER COMMON OWNERSHIP OR CONTROL WITHIN 24 MONTHS OF THE DATE OF THE APPLICATION, THE FIRST TWO LICENSING SURVEYS AS OF THE CHANGE OF OWNERSHIP DATE, SHALL BE EXCLUDED.

(V) CURRENTLY LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES

(VI) OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP).

(B) AN APPLICANT WILL CONTINUE TO OPERATE THE EXISTING NURSING HOME/HLTCU PURSUANT TO THE NEW DESIGN MODEL REQUIREMENTS.

(C) THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, SUCH AS MY INNERVIEW, ADVANCING EXCELLENCE, OR ANOTHER COMPARABLE PROGRAM FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE OMBUDSMAN, BUREAU OF HEALTH SYSTEMS, AND SHALL POST THE ANNUAL REPORT IN THE

FACILITY IF THE FACILITY BEING ACQUIRED HAS MET ANY OF CONDITIONS IN SUBSECTIONS (A)(I), (II), (III), (IV), (V), OR (VI).

(D) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

(3) AN APPLICANT PROPOSING TO RENEW THE LEASE FOR AN EXISTING NURSING HOME/HLTCU SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED NURSING HOME BED SUPPLY SET FORTH IN APPENDIX B FOR THE PLANNING AREA IN WHICH THE NURSING HOME/HLTCU IS LOCATED, IF THE APPLICANT DEMONSTRATES ALL OF THE FOLLOWING:

(A) THE LEASE RENEWAL WILL NOT RESULT IN A CHANGE IN BED CAPACITY,

(B) THE LICENSED SITE DOES NOT CHANGE AS A RESULT OF THE LEASE RENEWAL, AND

(C) A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY, IF ANY, HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT. CODE DEFICIENCES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT.

Section 10. Review standards for comparative review

Sec. 10 (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a), AND (b)~~, and (c)~~.

(a) A qualifying project will be awarded points, in ~~accord~~ ACCORDANCE with the schedule set forth below~~,~~:

(I) FOR AN EXISTING NURSINE HOME/HLTCU, THE ~~based on the nursing home's/HLTCU's proposed~~ CURRENT percentage of the nursing home's/HLTCU's patient days of care ~~to be~~ reimbursed by Medicaid ~~(calculated using total patient days for all existing and proposed beds at the facility)~~ for the MOST RECENT ~~second~~ 12 months of operation ~~following project completion, and annually for at least seven years thereafter~~.

(II) FOR A NEW NURSING HOME/HLTCU, THE PROPOSED PERCENTAGE OF THE NURSING HOME/HLTCU'S PATIENT DAYS OF CARE TO BE REIMBURSED BY MEDICAID IN THE SECOND 12 MONTHS OF OPERATION FOLLOWING PROJECT COMPLETION, AND ANNUALLY, THEREAFTER, FOR AT LEAST SEVEN YEARS.

~~Proposed~~ Percentage of Medicaid Patient Days (CALCULATED USING TOTAL PATIENT DAYS FOR ALL EXISTING AND PROPOSED BEDS AT THE FACILITY)	Points Awarded
0	0
1 ~~-~~ 19	~~1~~3
20 ~~-~~ 29	~~2~~6
40 ~~-~~ 59	~~3~~9
60 ~~-~~ 100	~~4~~12

~~(b) A qualifying project will be awarded points, in accord with the schedule set forth below, based~~

~~on the nursing home's/HLTCU's proposed percentage, for the second 12 months of operation following project completion and annually for at least seven years thereafter, of all of the nursing home's/HLTCU's newly admitted patients (not including readmissions) that will be Medicaid recipients or Medicaid eligible recipients.~~

~~Proposed Percentage of Medicaid Admissions~~	~~Points Awarded~~
~~0~~	~~0~~
~~1 - 5~~	~~1~~
~~6 - 15~~	~~2~~
~~16 - 30~~	~~3~~
~~31 - 100~~	~~4~~

(~~c~~B) A qualifying project will be awarded POINTS AS FOLLOWS:

(I) ~~three~~ NINE (~~3~~9) points if, ~~within six months of beginning operation and for at least seven years thereafter,~~ 100% ~~percent (100%)~~, SIX (6) POINTS IF 75%, AND THREE (3) POINTS IF 50% of the licensed nursing home beds at the facility ~~(both existing and proposed) will be~~ ARE Medicaid certified ~~IN~~ FOR THE MOST RECENT 12 MONTHS FOR AN EXISTING NURSING HOME/HLTCU.

(II) NINE (9) POINTS IF 100%, SIX POINTS IF 75%, AND THREE (3) POINTS IF 50% OF THE PROPOSED BEDS AT THE FACILITY WILL BE MEDICAID CERTIFIED FOR A NEW NURSING HOME/HLTCU.

(3) A qualifying project will be awarded points, in ~~accord~~ ACCORDANCE with the schedule set forth below, based on ~~its~~ THE MOST RECENT 12 MONTHS OF ~~proposed~~ participation LEVEL in the Medicare program FOR AN EXISTING NURSING HOME/HLTCU AND THE PROPOSED PARTICIPATION LEVEL FOR A NEW NURSING HOME/HLTCU ~~within six months of beginning operation and annually for at least seven years thereafter, including both physically conforming existing and proposed beds~~.

~~Proposed~~ Participation LEVEL	Points Awarded
No Medicare certification of any physically conforming existing and proposed beds.	0
Medicare certification of at least one (1) bed but less than 100% of all physically conforming existing and proposed beds.	1
Medicare certification of 100% of all physically conforming existing and proposed beds.	2

(4) A qualifying project will have points deducted based on the applicant's record of compliance with applicable federal and state safety and operating standards for any nursing home/HLTCU owned and/or operated by the applicant in Michigan. Points shall be deducted in accord with the schedule set forth below if, AFTER JULY 11, 1993~~following the effective date of these standards~~, the records which are

maintained by the Department document (a) any nonrenewal or revocation of license for cause and/or (b) nonrenewal or termination for cause of either Medicare or Medicaid certification of any Michigan nursing home/HLTCU owned and/or operated by the applicant.

Nursing Home/HLTCU Compliance Action	Points Deducted
Nonrenewal or revocation of license	~~2~~4
Nonrenewal or termination of:	
Certification - Medicare	~~2~~4
Certification - Medicaid	~~2~~4

~~(5) A qualifying project will be awarded two points if, following project completion, the applicant will provide either directly or through contractual relationships, as part of its living or housing arrangements, a home for the aged, an adult foster care home, or independent housing located on the same site or in the same planning area.~~

(5) A QUALIFYING PROJECT WILL BE AWARDED NINE (9) POINTS, IF THE APPLICANT CURRENTLY PROVIDES OR DEMONSTRATES THAT IT WILL PARTICIPATE IN A CULTURE CHANGE MODEL, WHICH CONTAINS PERSON CENTERED CARE, ONGOING STAFF TRAINING, AND MEASUREMENTS OF OUTCOMES.

~~(6) A qualifying project will be awarded points based on the applicant's "Total proposed project cost per bed," in accord with the schedule set forth below, (where "A" represents "Average total proposed project cost per bed"):~~

~~Range of "Total proposed project cost per bed"~~	~~Points Awarded~~
~~0 to (A minus $3000)~~	~~5~~
~~(A minus $2999) to (A minus $1000)~~	~~4~~
~~(A minus $999) to (A plus $1000)~~	~~3~~
~~(A plus $1001) to (A plus $5000)~~	~~2~~
~~(A plus $5001) to (A plus $11,000)~~	~~1~~
~~Above (A plus $11,000)~~	~~0~~

(~~7~~6) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the ~~"~~Total proposed project cost~~"~~ in accord with the schedule set forth below:

Percentage “Applicant’s Cash”	Points Awarded
Over 20 percent	~~5~~10
15.1 to 20 percent	~~4~~8
10.1 to 15 percent	~~3~~6
5.1 to 10 percent	~~2~~4
1.1 to 5 percent	~~1~~2
0 to 1 percent	0

(7) A QUALIFYING PROJECT WILL BE AWARDED SIX (6) POINTS IF, THE EXISTING OR PROPOSED NURSING HOME IS FULLY EQUIPPED WITH SPRINKLERS.

(8) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE FACILITY DESIGN

OF THE EXISTING OR PROPOSED NURSING HOME:

FACILITY DESIGN	POINTS AWARDED
80% PRIVATE ROOMS WITH PRIVATE TOILET AND SINK, AND CENTRAL SHOWERS WITH ADJACENT PRIVATE CHANGING ROOM FOR THE RESIDENT TO DRESS AND UNDRESS IN PRIVACY	6
80% PRIVATE ROOMS WITH PRIVATE TOILET, SINK, AND SHOWER	6
80% PRIVATE ROOMS WITH PRIVATE SINK, SHARED TOILET, AND CENTRAL SHOWERS WITH ADJACENT PRIVATE CHANGING ROOM FOR THE RESIDENT TO DRESS AND UNDRESS IN PRIVACY	3

~~(8) qualifying project will be awarded points for the following financing category:~~

~~Financing Category~~	~~Points Awarded~~
~~Interest only payments after the period of construction~~	~~0~~
~~Payment of principal and interest after the period of construction, according to an amortization schedule~~	~~2~~

(~~9~~10) THE MINIMUM NUMBER OF ~~No~~ points will be awarded to an applicant under THE INDIVIDUAL SUBSECTIONS OF THIS ~~specific subsections of~~ Section ~~10 if~~ FOR CONFLICTING information presented in THIS Section AND ~~10 is inconsistent with~~ related information provided in other ~~portions~~ SECTIONS of the CON application.

~~(10) The standards set forth in this section are assigned the weights listed below, with a weight of "1" being important, a weight of "2" being more important, and a weight of "3" being very important. The points awarded to an applicant in each of the subsections shall be multiplied by the applicable weight set forth below to determine the total number of points awarded to each applicant for each subsection.~~

~~Subsection~~	~~Weight~~
~~2(a)~~	~~3~~
~~2(b)~~	~~3~~
~~2(c)~~	~~3~~
~~3~~	~~1~~
~~4~~	~~2~~
~~5~~	~~1~~
~~6~~	~~2~~
~~7~~	~~2~~
~~8~~	~~1~~

(~~11~~11) The Department shall approve those qualifying projects which, taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through

(~~10~~10) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp ~~placed~~ on the application ~~for CON form (form T-150-G-1.01 or any subsequent replacement form) by the Health Facilities Section, CON~~, when the application is filed.

Section 11. Project delivery requirements -- terms of approval for all applicants

Sec. 11. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards, including the requirements of Section 10.

(b) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. ~~Compliance with Section 10(2)(b) shall be determined by comparing the actual number of Medicaid recipients and Medicaid eligible recipients who were newly admitted, as a percentage of all patients newly admitted to the nursing home/HLTCU, with the applicable schedule set forth in Section 10(2)(b) for which the applicant had been awarded points in the comparative review process.~~ If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a) ~~or (b)~~, instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Community Health [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA provided to the Department by the Michigan Department of Community Health.

(c) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) ~~and (b)~~ for which the seller or other previous owner/lessee had been awarded points in a comparative review.

(d) Compliance with applicable operating standards.

(e) Compliance with the following quality assurance standards:

(i) For projects involving replacement ~~beds~~ OF AN EXISTING NURSING HOME/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(ii) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost

information; operating schedules; and demographic, diagnostic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on an individual basis for each licensed site, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) The applicant shall provide the Department with a notice stating the date the beds are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) AN APPLICANT SHALL AGREE THAT, IF APPROVED, AND MATERIAL DISCREPENCIES ARE LATER DETERMINED WITHIN THE REPORTING OF THE OWNERSHIP AND CITATION HISTORY OF THE APPLICANT FACILITY AND ALL NURSING HOMES UNDER COMMON OWNERSHIP AND CONTROL THAT WOULD HAVE RESULTED IN A DENIAL OF THE APPLICATION, SHALL SURRENDER THE CON. THIS DOES NOT PRECLUDE AN APPLICANT FROM REAPPLYING WITH CORRECTED INFORMATION AT A LATER DATE.

(~~2~~3) The agreements and assurances required by this section shall be in the form of a certification AGREED TO BY THE ~~authorized by the governing body of the~~ applicant or its authorized agent.

Section 12. Department inventory of beds

Sec. 12. The Department shall maintain~~, and provide on request,~~ a listing of the Department Inventory of Beds for each planning area.

Section 13. Wayne County planning areas

Sec. 13. (1) For purposes of these standards the cities and/or townships in Wayne County are assigned to the planning areas as follows:

Planning Area 84/Northwest Wayne

Canton Township, Dearborn, Dearborn Heights, Garden City, Inkster, Livonia, Northville (part), Northville Township, Plymouth, Plymouth Township, Redford Township, Wayne, Westland

Planning area 85/Southwest Wayne

Allen Park, Belleville, Brownstown Township, Ecorse, Flat Rock, Gibraltar, Grosse Ile Township, Huron Township, Lincoln Park, Melvindale, River Rouge, Riverview, Rockwood, Romulus, Southgate, Sumpter Township, Taylor, Trenton, Van Buren Township, Woodhaven, Wyandotte

Planning area 86/Detroit

Detroit, Grosse Pointe, Grosse Pointe Township, Grosse Pointe Farms, Grosse Pointe Park, Grosse Pointe Woods, Hamtramck, Harper Woods, Highland Park

~~(2) A map showing the planning areas as listed in subsection (1) shall be available from the Department.~~

Section 14. Health Service Areas

Sec. 14. Counties assigned to each of the HSAs are as follows:

HSA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 15. Effect on prior CON review standards, comparative reviews

Sec. 15. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit Beds approved by the CON Commission on ~~March 9, 2004~~ SEPTEMBER 14, 2004 and effective on ~~June 4, 2004~~ DECEMBER 2, 2004.

(2) Projects reviewed under these standards~~,~~ involving a change in bed capacity~~,~~ shall be subject to comparative review except ~~for replacement beds being replaced within the replacement zone.~~ AS FOLLOWS:

(A) REPLACEMENT OF AN EXISTING NURSING HOME/HLTCU BEING REPLACED IN A RURAL COUNTY;

(B) REPLACEMENT OF AN EXISTING NURSING HOME/HLTCU IN A MICROPOLITAN OR METROPOLITAN STATISTICAL AREA COUNTY THAT IS WITHIN TWO MILES OF THE EXISTING

NURSING HOME/HLTCU;
(C) RELOCATION OF EXISTING NURSING HOME/HLTCU BEDS; OR
(D) AN INCREASE IN BEDS PURSUANT TO SECTION 6 (1)(D)(II) OR (III).

(3) Projects reviewed under these standards that relate solely to the acquisition of ~~a new~~ AN EXISTING nursing home ~~or~~ /HLTCU OR THE RENEWAL OF A LEASE shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The use rate per 1000 population for each age cohort, for purposes of these standards, until otherwise changed by the Commission, is as follows.

(i) age 0 - 64: ~~209~~ 170 days of care

(ii) age 65 - 74: ~~4,165~~ 3,126 days of care

(iii) age 75 - 84: ~~19,459~~ 10,987 days of care

(iv) age 85 +: ~~54,908~~ 37,368 days of care

APPENDIX B

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The bed need numbers, for purposes of these standards, until otherwise changed by the Commission, are as follows:

Planning Area	Bed Need	~~Department Inventory *~~	ADC Adjustment Factor
ALCONA	~~102~~ 88	~~106~~	0.90
ALGER	~~70~~ 68	~~106~~	0.90
ALLEGAN	~~474~~ 426	~~565~~	0.95
ALPENA	~~203~~ 173	~~208~~	0.95
ANTRIM	~~134~~ 142	~~113~~	0.95
ARENAC	~~106~~ 112	~~148~~	0.~~90~~95
BARAGA	~~72~~ 50	~~87~~	0.90
BARRY	~~262~~ 252	~~252~~	0.95
BAY	~~638~~ 552	~~668~~	0.95
BENZIE	~~93~~ 118	~~102~~	0.~~90~~95
BERRIEN	~~965~~ 790	~~899~~	0.95
BRANCH	~~241~~ 222	~~283~~	0.95
CALHOUN	~~805~~ 651	~~850~~	0.95
CASS	~~272~~ 234	~~222~~	0.95
CHARLEVOIX	~~134~~ 152	~~134~~	0.95
CHEBOYGAN	~~154~~ 181	~~162~~	0.95
CHIPPEWA	~~193~~ 189	~~173~~	0.95
CLARE	~~173~~ 163	~~200~~	0.95
CLINTON	~~251~~ 268	~~251~~	0.95
CRAWFORD	~~85~~ 104	~~160~~	0.~~90~~95
DELTA	~~260~~ 234	~~292~~	0.95
DICKINSON	~~230~~ 174	~~256~~	0.95
EATON	~~431~~ 472	~~444~~	0.95
EMMET	~~167~~ 172	~~230~~	0.95
GENESEE	~~1,951~~ 1,938	~~1,951~~	0.95
GLADWIN	~~150~~ 170	~~180~~	0.95
GOGEBIC	~~195~~ 114	~~221~~	0.95
GD. TRAVERSE	~~368~~ 410	~~552~~	0.95
GRATIOT	~~272~~ 255	~~556~~	0.95

~~* Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.~~

APPENDIX B - continued

Planning Area	Bed Need	~~Department Inventory *~~	ADC Adjustment Factor
HILLSDALE	~~262~~ 218	~~262~~	0.95
HOUGHTON/KEWEENAW	~~314~~168	~~335~~	0.95
HURON	~~278~~ 226	~~313~~	0.95
INGHAM	~~1,180~~ 1,161	~~1,028~~	0.95
IONIA	~~275~~ 258	~~248~~	0.95
IOSCO	~~193~~ 207	~~243~~	0.95
IRON	~~150~~ 101	~~149~~	0.95
ISABELLA	~~214~~ 244	~~309~~	0.95
JACKSON	~~828~~ 794	~~847~~	0.95
KALAMAZOO	~~1,120~~ 1,069	~~1,154~~	0.95
KALKASKA	~~76~~ 81	~~88~~	0.90
KENT	~~2,566~~ 2,388	~~2,495~~	0.95
LAKE	~~78~~ 83	~~89~~	0.90
LAPEER	~~291~~ 352	~~292~~	0.95
LEELANAU	~~111~~ 136	~~110~~	0.~~90~~95
LENAWEE	~~497~~ 487	~~497~~	0.95
LIVINGSTON	~~421~~ 592	~~475~~	0.95
LUCE	46	~~61~~	0.90
MACKINAC	~~81~~ 79	~~79~~	0.90
MACOMB	~~3,636~~ 4,305	~~3,933~~	0.95
MANISTEE	~~170~~ 154	~~221~~	0.95
MARQUETTE	~~361~~ 282	~~441~~	0.95
MASON	~~197~~ 166	~~202~~	0.95
MECOSTA	~~184~~ 212	~~232~~	0.95
MENOMINEE	~~197~~ 140	~~179~~	0.95
MIDLAND	~~338~~ 395	~~414~~	0.95
MISSAUKEE	~~81~~ 91	~~95~~	0.90
MONROE	~~619~~ 645	~~595~~	0.95
MONTCALM	~~285~~ 253	~~202~~	0.95
MONTMORENCY	~~89~~ 99	~~104~~	0.90
MUSKEGON	~~904~~ 779	~~917~~	0.95
NEWAYGO	~~222~~ 219	~~245~~	0.95

~~* Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.~~

APPENDIX B - continued

Planning Area	Bed Need	~~Department Inventory *~~	ADC Adjustment Factor
OAKLAND	~~5,241~~ 5,326	~~5,189~~	0.95
OCEANA	~~130~~ 124	~~113~~	0.95
OGEMAW	~~131~~ 144	~~233~~	0.95
ONTONAGON	~~76~~ 48	~~110~~	0.90
OSCEOLA	~~118~~ 106	~~54~~	0.95
OSCODA	~~69~~ 85	~~90~~	0.90
OTSEGO	~~111~~ 139	~~154~~	0.~~90~~95
OTTAWA	~~874~~ 1,060	~~796~~	0.95
PRESQUE ISLE	~~111~~ 115	~~126~~	0.95
ROSCOMMON	~~171~~ 186	~~179~~	0.95
SAGINAW	~~1,156~~ 1,039	~~1,175~~	0.95
ST. CLAIR	~~789~~ 754	~~722~~	0.95
ST. JOSEPH	~~355~~ 289	~~369~~	0.95
SANILAC	~~269~~ 231	~~287~~	0.95
SCHOOLCRAFT	~~72~~ 58	~~75~~	0.90
SHIAWASSEE	350	~~327~~	0.95
TUSCOLA	~~292~~ 270	~~293~~	0.95
VAN BUREN	~~411~~ 325	~~424~~	0.95
WASHTENAW	~~1,032~~ 1,146	~~1,285~~	0.95
WEXFORD	~~161~~ 168	~~209~~	0.95
NW WAYNE	~~3,166~~ 2,563	~~3,153~~	0.95
SW WAYNE	~~1,818~~ 1,732	~~2,028~~	0.95
DETROIT	~~6,297~~ 4,435	~~5,983~~	0.95

~~* Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.~~

APPENDIX C

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS

MICHIGAN NURSING HOME PLANNING AREAS WITH A POPULATION DENSITY OF LESS THAN 28 INDIVIDUALS PER SQUARE MILE BASED ON 2000 U.S. CENSUS FIGURES.

PLANNING AREA	POPULATION DENSITY PER SQUARE MILE
ONTONAGON	6.0
SCHOOLCRAFT	7.6
LUCE	7.8
BARAGA	9.7
ALGER	10.7
IRON	11.3
MACKINAC	11.7
OSCODA	16.7
ALCONA	17.4
GOGEBIC	15.8
MONTMORENCY	18.8
LAKE	20.0
PRESQUE ISLE	21.8
MENOMINEE	24.3
CHIPPEWA	24.7
HOUGHTON/KEWEENAW	24.7
MISSAUKEE	25.5
CRAWFORD	25.6

SOURCE: MICHIGAN DEPARTMENT OF MANAGEMENT AND BUDGET AND THE U.S. BUREAU OF THE CENSUS

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7, and ~~6~~ 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:

(A) "BEHAVIORAL PATIENT" MEANS AN INDIVIDUAL THAT EXHIBITS A HISTORY OF CHRONIC BEHAVIOR MANAGEMENT PROBLEMS SUCH AS AGGRESSIVE BEHAVIOR THAT PUTS SELF OR OTHERS AT RISK FOR HARM, OR AN ALTERED STATE OF CONSCIOUSNESS, INCLUDING PARANOIA , DELUSIONS, AND ACUTE CONFUSION.

(~~a~~B) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 et seq.

(~~b~~C) "Infection control program," ~~for purposes of Section 4(7),~~ means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(~~c~~D) "Licensed hospital" ~~for purposes of Section 3(6) of this addendum,~~ means either ~~:~~

~~(i)~~ a hospital licensed under Part 215 of the Code; or

~~(ii)~~ a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

~~(d) "Organized program," for purposes of sections 3(8) and 4(7), means a program operated by an applicant at the location at which the proposed nursing home beds will be operated that is consistent with the requirements of Section 4(7)(a) through (e), except Section 4(7)(c)(iv).~~

(e) "Private residence" ~~for purposes of Section 3(6) of this addendum~~, means a setting other than ~~:~~

~~(i)~~ a licensed hospital; or

~~(ii)~~ a nursing home including a nursing home or part of a nursing home approved pursuant to Section ~~3(6)~~6.

(F) "TRAUMATIC BRAIN INJURY (TBI)/SPINAL CORD INJURY (SCI) PATIENT" MEANS AN INDIVIDUAL WITH TBI OR SCI THAT IS ACQUIRED OR DUE TO A TRAUMATIC INSULT TO THE BRAIN AND ITS RELATED PARTS THAT IS NOT OF A DEGENERATIVE OR CONGENITAL NATURE. THESE IMPAIRMENTS MAY BE EITHER TEMPORARY OR PERMANENT AND CAUSE PARTIAL OR TOTAL FUNCTIONAL DISABILITY OR PSYCHOSOCIAL ADJUSTMENT.

(~~f~~G) "Ventilator-dependent patient," ~~for purposes of sections 3(8) and 4(7),~~ means ~~a patient who does not require acute inpatient hospital services and either:~~ AN INDIVIDUAL WHO REQUIRES MECHANICAL VENTILATORY ASSISTANCE.

~~(i) requires mechanical ventilatory assistance for a minimum of 6 hours each day; or~~
~~(ii) is being weaned from ventilatory dependency~~.

Section 2. Requirements for approval -- applicants proposing to increase nursing home beds -- special use exceptions

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to ~~Section 3 of~~ this addendum.

Section 3. Statewide pool for the needs of special population groups within the long-term care and nursing home populations

Sec. 3. (1) A statewide pool of additional nursing home beds of ~~2.0% of the~~ 1,958 beds needed in the state ~~through application of the bed need methodology in the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds~~ is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated ~~in accordance with subsections 3(a), 4(a), 5(a), and 6(a).~~ AS FOLLOWS:

(A)THESE CATEGORIES SHALL BE ALLOCATED 1,109 BEDS AND DISTRIBUTED AS FOLLOWS AND SHALL BE REDUCED/REDISTRIBUTED IN ACCORDANCE WITH SUBSECTION (C):

(I) TBI/SCI BEDS WILL BE ALLOCATED 400 BEDS.

(II) BEHAVIORAL BEDS WILL BE ALLOCATED 400 BEDS.

(III) HOSPICE BEDS WILL BE ALLOCATED 130 BEDS.

(IV) VENTILATOR DEPENDENT BEDS WILL BE ALLOCATED 179 BEDS.

(B)THE FOLLOWING HISTORICAL CATEGORIES HAVE BEEN ALLOCATED 849 BEDS. ADDITIONAL BEDS SHALL NOT BE ALLOCATED TO THESE CATEGORIES. IF THE BEDS WITHIN ANY OF THESE CATEGORIES ARE DELICENSED, THE BEDS SHALL BE ELIMINATED AND NOT BE RETURNED TO THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS.

(I) ALZHEIMER'S DISEASE HAS 384 BEDS.

(II) HEALTHCARE NEEDS FOR SKILLED NURSING CARE HAS 173 BEDS.

(III) RELIGIOUS HAS 292 BEDS.

(C) THE NUMBER OF BEDS SET ASIDE FROM THE TOTAL STATEWIDE POOL ESTABLISHED FOR CATEGORIES IN SUBSECTION (1)(A) FOR A SPECIAL POPULATION GROUP SHALL BE REDUCED IF THERE HAS BEEN NO CON ACTIVITY FOR THAT SPECIAL POPULATION GROUP DURING AT LEAST 6 CONSECUTIVE APPLICATION PERIODS.

(I) THE NUMBER OF BEDS IN A SPECIAL POPULATION GROUP SHALL BE REDUCED TO THE TOTAL NUMBER OF BEDS FOR WHICH A VALID CON HAS BEEN ISSUED FOR THAT SPECIAL POPULATION GROUP.

(II) THE NUMBER OF BEDS REDUCED FROM A SPECIAL POPULATION GROUP PURSUANT TO THIS SUBSECTION SHALL REVERT TO THE TOTAL STATEWIDE POOL ESTABLISHED FOR CATEGORIES IN SUBSECTION (1)(A).

(III) THE DEPARTMENT SHALL NOTIFY THE COMMISSION OF THE DATE WHEN ACTION TO REDUCE THE NUMBER OF BEDS SET ASIDE FOR A SPECIAL POPULATION GROUP HAS BECOME EFFECTIVE AND SHALL IDENTIFY THE NUMBER OF BEDS THAT REVERTED TO THE TOTAL STATEWIDE POOL ESTABLISHED FOR CATEGORIES IN SUBSECTION (1)(A).

(IV) FOR PURPOSES OF THIS SUBSECTION, "APPLICATION PERIOD" MEANS THE PERIOD OF TIME FROM ONE DESIGNATED APPLICATION DATE TO THE NEXT SUBSEQUENT DESIGNATED APPLICATION DATE.

(V) FOR PURPOSES OF THIS SUBSECTION, "CON ACTIVITY" MEANS ONE OR MORE OF THE FOLLOWING:

(A) CON APPLICATIONS FOR BEDS FOR A SPECIAL POPULATION GROUP HAVE BEEN SUBMITTED TO THE DEPARTMENT FOR WHICH EITHER A PROPOSED OR FINAL DECISION HAS

NOT YET BEEN ISSUED BY THE DEPARTMENT.

(B) ADMINISTRATIVE HEARINGS OR APPEALS TO COURT OF DECISIONS ISSUED ON CON APPLICATIONS FOR BEDS FOR A SPECIAL POPULATION GROUP ARE PENDING RESOLUTION.

(C) AN APPROVED CON FOR BEDS FOR EACH SPECIAL POPULATION GROUP HAS EXPIRED FOR LACK OF APPROPRIATE ACTION BY AN APPLICANT TO IMPLEMENT AN APPROVED CON.

(D) BY SETTING ASIDE THESE BEDS FROM THE TOTAL STATEWIDE POOL, THE COMMISSION'S ACTION APPLIES ONLY TO APPLICANTS SEEKING APPROVAL OF NURSING HOME BEDS PURSUANT TO SECTIONS 4, 5, 6, AND 7. IT DOES NOT PRECLUDE THE CARE OF THESE PATIENTS IN UNITS OF HOSPITALS, HOSPITAL LONG-TERM CARE UNITS, NURSING HOMES, OR OTHER HEALTH CARE SETTINGS IN COMPLIANCE WITH APPLICABLE STATUTORY OR CERTIFICATION REQUIREMENTS.

(2) Increases in nursing home beds approved under this addendum for special population groups shall not cause planning areas currently showing an unmet bed need to have that need reduced or planning areas showing a current surplus of beds to have that surplus increased.

~~(3)(a) The CON Commission determines there is a need for beds for religious needs for specialized services within the long-term care and nursing home populations and sets aside 302 beds from the total statewide pool established in subsection (1) to address this need. Those needs are defined as being met by those applications meeting the requirements of subsection (3)(b) or (c).~~

~~(b) An applicant proposing nursing home beds allocated under this subsection due to migration of the patient population shall demonstrate with credible documentation to the satisfaction of the Department each of the following:~~

~~(i) The applicant is currently licensed to operate a nursing home in Michigan and the application is for replacement and/or relocation of an existing licensed facility.~~

~~(ii) The number of beds proposed for replacement must be equal to or less than the licensed capacity of the applicant's existing nursing home on the date on which the CON application is filed.~~

~~(iii) The facility to be replaced does not meet licensing or certification standards for health facilities as determined by the Department.~~

~~(iv) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under Section 501(c)(3) of the United States Internal Revenue Code.~~

~~(v) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.~~

~~(vi) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.~~

~~(vii) The replacement project responds to demographic changes, verifiable by the Department, which have decreased the representation of members of the religious organization or denomination in the planning area of the facility to be replaced and which have increased the representation of the members of the religious organization or denomination in the planning area of the replacement facility.~~

~~(viii) An applicant proposing replacement beds shall not be required to be in compliance with Section 8 (b) of the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, or any subsequent standard approved which requires the proposed new licensed site to be in the replacement zone.~~

~~(c) An applicant proposing to add nursing home beds allocated under this subsection for a project other than described in subsection (b) shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:~~

~~(i) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under Section 501(c)(3) of the United States Internal Revenue Code.~~

~~(ii) The applicant's proposed patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.~~

~~(iii) The applicant's proposed services and/or operations are tailored to meet certain special needs of a specific religion, denomination, or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.~~

SECTION 4. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO TBI/SCI PATIENTS

SEC. 4 THE CON COMMISSION DETERMINES THERE IS A NEED FOR BEDS FOR APPLICATIONS DESIGNED TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF SPECIALIZED PROGRAMS FOR THE CARE AND TREATMENT OF TBI/SCI PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL NURSING HOME UNIT(S).

(1) AN APPLICANT PROPOSING TO BEGIN OPERATION OF A NEW NURSING HOME/HLTCU OR ADD BEDS TO AN EXISTING NURSING HOME/HLTCU UNDER THIS SECTION SHALL DEMONSTRATE WITH CREDIBLE DOCUMENTATION TO THE SATISFACTION OF THE DEPARTMENT EACH OF THE FOLLOWING:

(A) THE BEDS WILL BE OPERATED AS PART OF A SPECIALIZED PROGRAM EXCLUSIVELY FOR TBI/SCI PATIENTS. AT THE TIME AN APPLICATION IS SUBMITTED, THE APPLICANT SHALL DEMONSTRATE THAT IT OPERATES:

(I) A CONTINUUM OF OUTPATIENT TREATMENT, REHABILITATIVE CARE, AND SUPPORT SERVICES FOR TBI/SCI PATIENTS; AND

(II) A TRANSITIONAL LIVING PROGRAM OR CONTRACTS WITH AN ORGANIZATION THAT OPERATES A TRANSITIONAL LIVING PROGRAM AND REHABILITATIVE CARE FOR TBI/SCI PATIENTS.

(B) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION OF ITS EXISTING OUTPATIENT AND/OR RESIDENTIAL PROGRAMS BY THE COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES (CARF) OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR REHABILITATIVE CARE AND SERVICES.

(C) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE NURSING HOME BEDS PROPOSED UNDER THIS SUBSECTION.

(D) A FLOOR PLAN FOR THE PROPOSED PHYSICAL PLANT SPACE TO HOUSE THE NURSING HOME BEDS ALLOCATED UNDER THIS SUBSECTION THAT PROVIDES FOR:

(I) INDIVIDUAL UNITS CONSISTING OF 20 BEDS OR LESS PER UNIT, NOT TO BE MORE THAN 40 BEDS PER FACILTY;

(II) DAY/DINING AREA WITHIN, OR IMMEDIATELY ADJACENT TO, THE UNIT(S), WHICH IS SOLELY FOR THE USE OF TBI/SCI PATIENTS.

(III) DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE FACILITY APPROPRIATE FOR SUPERVISED ACTIVITY.

(E) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR TBI/SCI PATIENTS OF VARIOUS AGES.

(2) BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS UNDER THE CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS AND SHALL NOT BE OFFERED TO INDIVIDUALS OTHER THAN TBI/SCI PATIENTS.

SECTION 5. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BEHAVIORAL PATIENTS

SEC. 5. The CON Commission determines there is a need for beds for applications designed to

determine the efficiency and effectiveness of specialized programs for the care and treatment of ~~persons with~~ BEHAVIORAL PATIENTS ~~Alzheimer's disease~~ as compared to serving these needs in general nursing home unit(s). ~~and designed to study the relationship between the needs of Alzheimer's disease patients and those of other non-specialized nursing home patients. The CON Commission sets aside 300 beds from the total statewide pool established in subsection (1) to address this need. Those needs are defined as being met by those applications meeting the requirements of subsection (4).~~

(~~b~~1) An applicant proposing TO BEGIN OPERATION OF A NEW NURSING HOME/HLTCU OR ADD BEDS TO AN EXISTING NURSING HOME/HLTCU ~~to add nursing home beds allocated~~ under this ~~sub~~section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

~~(i) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.~~

~~(ii)The specialized program will participate in the state registry for Alzheimer's disease.~~

~~(iii)The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.~~

(A) INDIVIDUAL UNITS SHALL CONSIST OF 20 BEDS OR LESS PER UNIT.

(B) THE FACILITY SHALL NOT BE AWARDED MORE THAN 40 BEDS;

(~~iv~~C) The proposed ~~Alzheimer's~~ unit shall have direct access to a secure outdoor or indoor area FOR SUPERVISED ACTIVITY ~~at the health facility, appropriate for unsupervised activity~~.

(~~v~~D) The ~~Alzheimer's~~ unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the ~~Alzheimer's unit~~ BEHAVIORAL patients.

(~~vi~~E) The physical environment of the ~~Alzheimer's~~ unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(~~vii~~F) ~~—~~Staff will be specially trained in ~~Alzheimer's disease~~ TREATMENT OF BEHAVIORAL PATIENTS. ~~treatment.~~

~~(viii) If the applicant has operated a specialized program and has demonstrated an occupancy rate of at least 97 percent in the Alzheimer's specialized unit(s) for the most recent, continuous 24-month period prior to submitting its application to the department, it may request up to an additional 20 beds but cannot exceed a total of 40 beds awarded from the statewide pool established in subsection (1).~~

~~(A) The specialized unit(s) shall be no larger than 20 beds.~~

~~(B) An applicant shall not be awarded more than a total of 40 beds.~~

(~~c~~2) Beds approved under this subsection shall not be converted to ~~non-specialized non-Alzheimer's~~ GENERAL NURSING HOME USE ~~long-term care services~~ without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

~~(5)(a) The CON Commission determines there is a need for beds for the health needs for skilled nursing care services within the long-term care and nursing home populations and sets aside 257 beds from the total statewide pool established in subsection (1) to address this need. Those needs are defined as being met by those applications meeting the requirements of subsection (5).~~

~~(b) An applicant proposing to add nursing home beds allocated under this subsection shall demonstrate with credible documentation to the satisfaction of the Department each of the following:~~

~~(i) The planning area in which the beds will be located shall have a population density of less than 28 individuals per square mile based on the 1990 U.S. Census figures as set forth in Appendix A.~~

~~(ii) An application for beds from the special statewide pool of beds shall not be approved if any application for beds in that planning area has been approved from the special statewide pool of beds under Section 3(5).~~

~~(iii) The average occupancy rate for the planning area in which the beds will be located shall have been at least 95% for each of the three most recent years for which the Department has either: annual survey data; or data reported to the Department for purposes of compiling the "Staffing/Bed Utilization~~

~~Ratios Report," whichever is the most recent data available. In determining the average occupancy rate for the planning area, the first six months of occupancy for any newly opened facility or newly opened part of a facility in that period shall be excluded.~~

~~(iv) An application shall not be approved if it proposes more than 40 beds.~~

~~(v) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.~~

SECTION 6. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO HOSPICE PATIENTS

SEC. 6. The CON Commission determines there is a need for beds for patients requiring both hospice and long-term nursing care services within the long-term care and nursing home populations. ~~and sets aside 100 beds from the total statewide pool established in subsection (1) to address this need. Those needs are defined as being met by those applications meeting the requirements of subsection (6).~~

(~~b~~1) An applicant proposing TO BEGIN OPERATION OF A NEW NURSING HOME/HLTCU OR ADD BEDS TO AN EXISTING NURSING HOME/HLTCU ~~to add nursing home beds allocated~~ under this ~~sub~~section shall demonstrate, with credible documentation to the satisfaction of the department, each of the following:

(~~i~~A) An applicant shall be a hospice certified by Medicare pursuant to the Code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.

(~~ii~~B) An applicant shall demonstrate that, during the most recent 12 month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.

(~~iii~~C) An application shall propose 30 beds or less.

(~~iv~~D) An applicant for beds from the special statewide pool of beds shall not be approved if any application for beds in that same planning area has been approved from the special statewide pool of beds ALLOCATED FOR HOSPICE ~~under Section 3(6)~~.

~~(v) An applicant shall submit, at the time an application is submitted to the Department, a study which documents, to the satisfaction of the Department, that both (A) and (B) have been contacted regarding the availability of either beds or space for acquisition (whether through purchase, lease or other comparable arrangement) for use by the proposed project, and that either: (1) beds or space are not available for acquisition; or (2) if beds or space are available for acquisition, the capital costs of developing the beds or space in the acquired space for use by the proposed project are higher than the applicant's proposed project costs.~~

~~(A) Each licensed hospital in the planning area.~~

~~(B) Each licensed nursing home or hospital long-term care unit in the planning area.~~

~~If an applicant does not receive a response from (A) or (B) within 30 days of the date of contact, an applicant shall demonstrate that contact was made by 1 certified mail return receipt for each organization contacted. The requirements of this subdivision shall not apply to nursing homes or hospital long-term care units that either:~~

~~(1) Have not been cited by the Department's Division of Licensing and Certification for 1 or more level a deficiencies during the 12 months prior to the date an application is submitted to the Department.~~

~~(2) Have been granted, by the Department, a waiver of 1 or more physical plant licensure requirements~~.

(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

~~(7)(a) The number of beds set aside from the total statewide pool established in subsection (1) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.~~

~~(b) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.~~

~~(c) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established in subsection (1).~~

~~(d) The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established in subsection (1).~~

~~(e) For purposes of this subsection, "application period" means the period of time from one designated application date to the next subsequent designated application date.~~

~~(f) For purposes of this subsection, "CON activity" means one or more of the following:~~

~~(i) CON applications for beds for a special population group have been submitted to the Department for which either a proposed or final decision has not yet been issued by the Department.~~

~~(ii) Administrative hearings or appeals to court of decisions issued on CON applications for beds for a special population group are pending resolution.~~

~~(iii) An approved CON for beds for each special population group has expired for lack of appropriate action by an applicant to implement an approved CON.~~

SECTION 7. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO VENTILATOR DEPENDENT PATIENTS

SEC. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations ~~and sets aside 0 beds from the total statewide pool established in subsection (1) to address this need. Those needs are defined as being met by those applications meeting the requirements of subsection (8). By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds pursuant to this subsection and does not preclude the care of ventilator dependent patients in units of hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with applicable statutory or certification requirements.~~

(~~b~~1) An applicant proposing to BEGIN OPERATION OF A NEW NURSING HOME/HLTCU OR ADD BEDS TO AN EXISTING NURSING HOME/HLTCU ~~add nursing home beds allocated~~ under this ~~sub~~section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(~~i~~A) An applicant PROPOSES ~~has an organized~~ A program for caring for ventilator-dependent patients in licensed ~~hospital~~ NURSING HOME beds~~, and has been recognized by the Department or the Michigan Department of Social Services as having provided an organized program for caring for ventilator-dependent patients for at least 30 continuous months prior to the date on which an application under this subsection is submitted to the Department.~~

(~~ii~~B) An application proposes no more than ~~15~~ 40 beds that will be licensed as nursing home beds~~ under Part 217 of the Code~~.

~~(iii) The proposed unit will be located in a hospital licensed under Part 215 of the Code.~~

~~(iv) An applicant for beds from this special statewide pool of beds shall not be approved if any application for beds in the same county has been approved from the special statewide pool of beds under Section 3(8).~~

(~~v~~C) The proposed unit will serve only ventilator-dependent patients.

~~(vi) An applicant shall delicense a number of licensed hospital beds equal to or than greater than the number of beds proposed pursuant to this subsection.~~

~~(vii) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.~~

(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

SECTION 8. ACQUISITION OF NURSING HOME/HLTCU BEDS APPROVED PURSUANT TO THIS ADDENDUM

Sec. 8. (1) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO RELIGIOUS SHALL MEET THE FOLLOWING:

(A) THE APPLICANT IS A PART OF, CLOSELY AFFILIATED WITH, CONTROLLED, SANCTIONED OR SUPPORTED BY A RECOGNIZED RELIGIOUS ORGANIZATION, DENOMINATION OR FEDERATION AS EVIDENCED BY DOCUMENTATION OF ITS FEDERAL TAX EXEMPT STATUS AS A RELIGIOUS CORPORATION, FUND, OR FOUNDATION UNDER SECTION 501(C)(3) OF THE UNITED STATES INTERNAL REVENUE CODE.

(B) THE APPLICANT'S PATIENT POPULATION INCLUDES A MAJORITY OF MEMBERS OF THE RELIGIOUS ORGANIZATION OR DENOMINATION REPRESENTED BY THE SPONSORING ORGANIZATION.

(C) THE APPLICANT'S EXISTING SERVICES AND/OR OPERATIONS ARE TAILORED TO MEET CERTAIN SPECIAL NEEDS OF A SPECIFIC RELIGION, DENOMINATION OR ORDER, INCLUDING UNIQUE DIETARY REQUIREMENTS, OR OTHER UNIQUE RELIGIOUS NEEDS REGARDING CEREMONY, RITUAL, AND ORGANIZATION WHICH CANNOT BE SATISFACTORILY MET IN A SECULAR SETTING.

(D) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

(2) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO TBI/SCI SHALL MEET THE FOLLOWING:

(A) THE BEDS WILL BE OPERATED AS PART OF A SPECIALIZED PROGRAM EXCLUSIVELY FOR TBI/SCI PATIENTS. AT THE TIME AN APPLICATION IS SUBMITTED, THE APPLICANT SHALL DEMONSTRATE THAT IT OPERATES:

(I) A CONTINUUM OF OUTPATIENT TREATMENT, REHABILITATIVE CARE, AND SUPPORT SERVICES FOR TBI/SCI PATIENTS; AND

(II) A TRANSITIONAL LIVING PROGRAM OR CONTRACTS WITH AN ORGANIZATION THAT OPERATES A TRANSITIONAL LIVING PROGRAM AND REHABILITATIVE CARE FOR TBI/SCI PATIENTS.

(B) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION OF ITS EXISTING OUTPATIENT AND/OR RESIDENTIAL PROGRAMS BY THE COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES (CARF) OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR REHABILITATIVE CARE AND SERVICES.

(C) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE NURSING HOME BEDS PROPOSED UNDER THIS SUBSECTION.

(D) A FLOOR PLAN FOR THE PROPOSED PHYSICAL PLANT SPACE TO HOUSE THE NURSING HOME BEDS ALLOCATED UNDER THIS SUBSECTION THAT PROVIDES FOR:

(I) INDIVIDUAL UNITS CONSISTING OF 20 BEDS OR LESS PER UNIT, NOT TO BE MORE THAN 40 BEDS PER FACILTY;

(II) DAY/DINING AREA WITHIN, OR IMMEDIATELY ADJACENT TO, THE UNIT(S), WHICH IS SOLELY FOR THE USE OF TBI/SCI PATIENTS.

(III) DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE FACILITY APPROPRIATE FOR SUPERVISED ACTIVITY.

(E) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR TBI/SCI PATIENTS OF VARIOUS AGES.

(3) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO ALZHEIMER'S DISEASE SHALL MEET THE FOLLOWING:

(A) THE BEDS ARE PART OF A SPECIALIZED PROGRAM FOR ALZHEIMER'S DISEASE WHICH WILL ADMIT AND TREAT ONLY PATIENTS WHICH REQUIRE LONG-TERM NURSING CARE

AND HAVE BEEN APPROPRIATELY CLASSIFIED AS A PATIENT ON THE GLOBAL DETERIORATION SCALE (GDS) FOR AGE-ASSOCIATED COGNITIVE DECLINE AND ALZHEIMER'S DISEASE AS A LEVEL 4 (WHEN ACCOMPANIED BY CONTINUOUS NURSING NEEDS), 5, OR 6.

(B) THE SPECIALIZED PROGRAM WILL PARTICIPATE IN THE STATE REGISTRY FOR ALZHEIMER'S DISEASE.

(C) THE SPECIALIZED PROGRAM SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A LICENSED NURSING HOME AND BE NO LARGER THAN 20 BEDS IN SIZE.

(D) THE PROPOSED ALZHEIMER'S UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE HEALTH FACILITY, APPROPRIATE FOR UNSUPERVISED ACTIVITY.

(E) THE ALZHEIMER'S UNIT SHALL HAVE WITHIN THE UNIT OR IMMEDIATELY ADJACENT TO IT A DAY/DINING AREA WHICH IS SOLELY FOR THE USE OF THE ALZHEIMER'S UNIT PATIENTS.

(F) THE PHYSICAL ENVIRONMENT OF THE ALZHEIMER'S UNIT SHALL BE DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

(G) STAFF WILL BE SPECIALLY TRAINED IN ALZHEIMER'S DISEASE TREATMENT.

(H) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

(4) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BEHAVIORAL PATIENTS SHALL MEET THE FOLLOWING:

(A)INDIVIDUAL UNITS SHALL CONSIST OF 20 BEDS OR LESS PER UNIT.

(B)THE FACILITY SHALL NOT BE AWARDED MORE THAN 40 BEDS;

(C) THE PROPOSED UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA FOR SUPERVISED ACTIVITY.

(D) THE UNIT SHALL HAVE WITHIN THE UNIT OR IMMEDIATELY ADJACENT TO IT A DAY/DINING AREA WHICH IS SOLELY FOR THE USE OF THE BEHAVIORAL PATIENTS.

(E) THE PHYSICAL ENVIRONMENT OF THE UNIT SHALL BE DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

(F) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF BEHAVIORAL PATIENTS.

(G) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

(5) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO HOSPICE SHALL MEET THE FOLLOWING:

(A) AN APPLICANT SHALL BE A HOSPICE CERTIFIED BY MEDICARE PURSUANT TO THE CODE OF FEDERAL REGULATIONS, TITLE 42, CHAPTER IV, SUBPART B (MEDICARE PROGRAMS), PART 418 AND SHALL HAVE BEEN A MEDICARE CERTIFIED HOSPICE FOR AT LEAST 24 CONTINUOUS MONTHS PRIOR TO THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) AN APPLICANT SHALL DEMONSTRATE THAT, DURING THE MOST RECENT 12 MONTH PERIOD PRIOR TO THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT, AT LEAST 64% OF THE TOTAL NUMBER OF HOSPICE DAYS OF CARE PROVIDED TO ALL OF THE CLIENTS OF THE APPLICANT HOSPICE WERE PROVIDED IN A PRIVATE RESIDENCE.

(C) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

(6) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO VENTILATOR DEPENDENT PATIENTS SHALL MEET THE FOLLOWING:

(A) AN APPLICANT PROPOSES A PROGRAM FOR CARING FOR VENTILATOR-DEPENDENT PATIENTS IN LICENSED NURSING HOME BEDS.
(B) AN APPLICATION PROPOSES NO MORE THAN 40 BEDS THAT WILL BE LICENSED AS NURSING HOME BEDS.
(C) THE PROPOSED UNIT WILL SERVE ONLY VENTILATOR-DEPENDENT PATIENTS.
(D) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

Section 49. Project delivery requirements -- terms of approval for all applicants seeking approval under Section 3(1) OF THIS ADDENDUM

Sec. 48. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

~~(2) In addition to the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(3)(b) shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following terms of CON approval:~~
~~(a) The applicant shall submit a resolution of its governing body certifying that it shall cease operations as a licensed health care facility at the existing licensed site, and that the license of the existing site which is replaced under Section 3(3) shall be surrendered to the Department concurrently with the licensure of a replacement facility approved under Section 3(3)(b).~~
~~(b) The applicant shall document, at the end of the third year following initiation of beds approved pursuant to Section 3(3)(b), an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.~~
~~(c) When opening, the replacement facility shall admit the current patients of the facility being replaced to the extent those patients desire to transfer to the replacement facility.~~

(~~3~~2) ~~In addition to the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(3)(c)~~ AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO RELIGIOUS shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term of CON approval:
(a) The applicant shall document, at the end of the third year following initiation of beds approved ~~pursuant to Section 3(3)(c)~~ an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.

(~~4~~3) ~~In addition to the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(4)~~ AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO ALZHEIMER'S DISEASE shall agree that if approved:
~~(a) The services provided by the specialized Alzheimer's disease beds shall be delivered in compliance with the requirements for approval in subsections 3(4)(a) and (b); and~~
~~(b) All beds approved pursuant to that subsection shall be certified for Medicaid.~~
(A) THE BEDS ARE PART OF A SPECIALIZED PROGRAM FOR ALZHEIMER'S DISEASE WHICH WILL ADMIT AND TREAT ONLY PATIENTS WHICH REQUIRE LONG-TERM NURSING CARE AND HAVE BEEN APPROPRIATELY CLASSIFIED AS A PATIENT ON THE GLOBAL DETERIORATION SCALE (GDS) FOR AGE-ASSOCIATED COGNITIVE DECLINE AND ALZHEIMER'S DISEASE AS A LEVEL 4 (WHEN ACCOMPANIED BY CONTINUOUS NURSING NEEDS), 5, OR 6.
(B) THE SPECIALIZED PROGRAM WILL PARTICIPATE IN THE STATE REGISTRY FOR

ALZHEIMER'S DISEASE.

(C) THE SPECIALIZED PROGRAM SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A LICENSED NURSING HOME AND BE NO LARGER THAN 20 BEDS IN SIZE.

(D) THE PROPOSED ALZHEIMER'S UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE HEALTH FACILITY, APPROPRIATE FOR UNSUPERVISED ACTIVITY.

(E) THE ALZHEIMER'S UNIT SHALL HAVE WITHIN THE UNIT OR IMMEDIATELY ADJACENT TO IT A DAY/DINING AREA WHICH IS SOLELY FOR THE USE OF THE ALZHEIMER'S UNIT PATIENTS.

(F) THE PHYSICAL ENVIRONMENT OF THE ALZHEIMER'S UNIT SHALL BE DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

(G) STAFF WILL BE SPECIALLY TRAINED IN ALZHEIMER'S DISEASE TREATMENT.

~~(5) In addition to the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(5) shall agree that if approved, all beds approved pursuant to that subsection shall be dually certified for Medicare and Medicaid.~~

(~~6~~4) ~~In addition to the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(6)~~ AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO HOSPICE shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.

(b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.

(c) An applicant ~~approved for nursing home beds pursuant to Section 3(6)~~ shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.

(d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds ~~approved pursuant to Section 3(6)~~.

(e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds ~~approved pursuant to Section 3(6)~~.

(f) Nursing home beds ~~approved pursuant to Section 3(6)~~ shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

(g) An applicant shall agree that the nursing home beds ~~approved pursuant to Section 3(6) of these standards~~ shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.

(h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.

(i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.

~~(j) An applicant shall annually provide data to determine the efficiency and effectiveness of providing, in a nursing home or hospital long-term care unit, room and board services to hospice clients that would otherwise be treated in a private residence if a capable primary caregiver was available. An applicant shall, at a minimum, provide data to the Department on a calendar year basis for each of the following:~~

~~(i) The number of hospice patients and associated days of care for general inpatient and respite inpatient hospice care;~~

~~(ii) The number of hospice patients and associated days of care for hospice routine and continuous~~

~~home care not provided in a nursing home or hospital long-term care unit; and~~

~~(iii) The number of hospice patients and associated days of care for hospice room and board in a nursing home.~~

~~(iv) The total number of hospice clients and associated days of care served by the applicant hospice which shall be the sum of subdivisions (i), (ii), and (iii).~~

~~These data shall be considered when revisions to these standards are considered. The Department shall annually report to the Commission a summary of the data collected pursuant to this requirement. At a minimum, the summary shall report the occupancy rate and average length of stay for each applicant approved pursuant to Section 3(6) of this addendum.~~

(~~7~~5) ~~In addition to the terms of approval required by the CON review standards for nursing home and hospital long-term care unit beds, an applicant for beds under Section 3(8)~~ AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO VENTILATOR DEPENDENT PATIENTS shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:

(i) a medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.

(ii) a program director that is a registered nurse.

(b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:

(i) respiratory therapy.

(ii) occupational and physical therapy.

(iii) psychological services.

(iv) family and patient teaching activities.

(c) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.

(ii) The transfer of patients requiring care at other health care facilities.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

(iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.

(v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.

(d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:

(i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.

(ii) placement and care of urinary catheters.

(iii) care and use of thermometers.

(iv) care and use of tracheostomy devices.

(v) employee personal hygiene.

(vi) aseptic technique.

(vii) care and use of respiratory therapy and related equipment.

(viii) isolation techniques and procedures.

(e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the

ventilator-dependent unit.

(f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.

~~(g) An applicant shall agree that all beds approved pursuant to Section 3(8) will be dually certified for Medicare and Medicaid reimbursement.~~

(~~h~~G) An applicant ~~approved for beds pursuant to Section 3(8)~~ shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.

(i) An applicant ~~approved for beds pursuant to Section 3(8)~~ shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.

(6) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO TBI/SCI PATIENTS SHALL AGREE THAT IF APPROVED:

(A) AN APPLICANT SHALL STAFF THE PROPOSED UNIT FOR TBI/SCI PATIENTS WITH EMPLOYEES THAT HAVE BEEN TRAINED IN THE CARE AND TREATMENT OF SUCH INDIVIDUALS AND INCLUDES AT LEAST THE FOLLOWING:

(I) A MEDICAL DIRECTOR WITH SPECIALIZED KNOWLEDGE, TRAINING, AND SKILLS IN THE CARE OF TBI/SCI PATIENTS.

(II) A PROGRAM DIRECTOR THAT IS A REGISTERED NURSE.

(III) OTHER PROFESSIONAL DISCIPLINES REQUIRED FOR A MULTI-DISCIPLINARY TEAM APPROACH TO CARE.

(B) AN APPLICANT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:

(I) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE UNIT FOR TBI/SCI PATIENTS. AT A MINIMUM, THE CRITERIA SHALL ADDRESS THE REQUIRED MEDICAL STABILITY AND THE NEED FOR ANCILLARY SERVICES, INCLUDING DIALYSIS SERVICES.

(II) THE TRANSFER OF PATIENTS REQUIRING CARE AT OTHER HEALTH CARE FACILITIES, INCLUDING A TRANSFER AGREEMENT WITH ONE OR MORE ACUTE-CARE HOSPITALS IN THE REGION TO PROVIDE EMERGENCY MEDICAL TREATMENT TO ANY PATIENT WHO REQUIRES SUCH CARE.

(III) UPON ADMISSION AND PERIODICALLY THEREAFTER, A COMPREHENSIVE NEEDS ASSESSMENT, A TREATMENT PLAN, AND A DISCHARGE PLAN THAT AT A MINIMUM ADDRESSES THE CARE NEEDS OF A PATIENT FOLLOWING DISCHARGE, INCLUDING SUPPORT SERVICES TO BE PROVIDED BY TRANSITIONAL LIVING PROGRAMS OR OTHER OUTPATIENT PROGRAMS OR SERVICES OFFERED AS PART OF A CONTINUUM OF CARE TO TBI PATIENTS BY THE APPLICANT.

(IV) UTILIZATION REVIEW, WHICH SHALL CONSIDER THE REHABILITATION NECESSITY FOR THE SERVICE, QUALITY OF PATIENT CARE, RATES OF UTILIZATION AND OTHER CONSIDERATIONS GENERALLY ACCEPTED AS APPROPRIATE FOR REVIEW.

(V) QUALITY ASSURANCE AND ASSESSMENT PROGRAM TO ASSURE THAT SERVICES FURNISHED TO TBI/SCI PATIENTS MEET PROFESSIONAL RECOGNIZED STANDARDS OF HEALTH CARE FOR PROVIDERS OF SUCH SERVICES AND THAT SUCH SERVICES WERE REASONABLE AND MEDICALLY APPROPRIATE TO THE CLINICAL CONDITION OF THE TBI PATIENT RECEIVING SUCH SERVICES.

(7) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BEHAVIORAL TBI/SCI PATIENTS SHALL AGREE THAT IF APPROVED:

(A) AN APPLICANT SHALL STAFF THE PROPOSED UNIT FOR BEHAVIORAL PATIENTS WITH EMPLOYEES THAT HAVE BEEN TRAINED IN THE CARE AND TREATMENT OF SUCH INDIVIDUALS AND INCLUDES AT LEAST THE FOLLOWING:

(I) A MEDICAL DIRECTOR WITH SPECIALIZED KNOWLEDGE, TRAINING, AND SKILLS IN THE CARE OF BEHAVIORAL PATIENTS.

(II) A PROGRAM DIRECTOR THAT IS A REGISTERED NURSE.
(III) OTHER PROFESSIONAL DISCIPLINES REQUIRED FOR A MULTI-DISCIPLINARY TEAM APPROACH TO CARE.
(B) AN APPLICANT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:
(I) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE UNIT FOR BEHAVIORAL PATIENTS.
(II) THE TRANSFER OF PATIENTS REQUIRING CARE AT OTHER HEALTH CARE FACILITIES, INCLUDING A TRANSFER AGREEMENT WITH ONE OR MORE ACUTE-CARE HOSPITALS IN THE REGION TO PROVIDE EMERGENCY MEDICAL TREATMENT TO ANY PATIENT WHO REQUIRES SUCH CARE.
(III) UTILIZATION REVIEW, WHICH SHALL CONSIDER THE REHABILITATION NECESSITY FOR THE SERVICE, QUALITY OF PATIENT CARE, RATES OF UTILIZATION AND OTHER CONSIDERATIONS GENERALLY ACCEPTED AS APPROPRIATE FOR REVIEW.
(IV) QUALITY ASSURANCE AND ASSESSMENT PROGRAM TO ASSURE THAT SERVICES FURNISHED TO BEHAVIORAL PATIENTS MEET PROFESSIONAL RECOGNIZED STANDARDS OF HEALTH CARE FOR PROVIDERS OF SUCH SERVICES AND THAT SUCH SERVICES WERE REASONABLE AND MEDICALLY APPROPRIATE TO THE CLINICAL CONDITION OF THE BEHAVIORAL RECEIVING SUCH SERVICES.
(V) ORIENTATION AND ANNUAL EDUCATION/COMPETENCIES FOR ALL STAFF, WHICH SHALL INCLUDE CARE GUIDELINES, SPECIALIZED COMMUNICATION, AND PATIENT SAFETY.

Section ~~5~~10. Comparative reviews, effect on prior CON review standards

Sec. ~~5~~10. (1) Projects proposed under Section ~~3(3)~~4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(2) Projects proposed under Section ~~3(4)~~5 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(3) Projects proposed under Section ~~3(5)~~6 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(4) Projects proposed under Section ~~3(6)~~7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

~~(5) Projects proposed under section 3(8) shall be considered a distinct category and shall be subject to comparative review on a statewide basis.~~

(6) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on ~~March 9, 2004~~ SEPTEMBER 14, 2004 and effective on ~~June 4, 2004~~ DECEMBER 3, 2004.

~~**Section 6. Acquisition of nursing home or hospital long-term care unit beds approved pursuant to this addendum.**~~

~~Sec. 6. (1) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved pursuant to Section 3(3)(b) or (c) of this addendum shall demonstrate that it is in compliance with the requirements of Section 3(3)(b)(iv), (v) and (vi) of this addendum.~~

~~(2) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved pursuant to Section 3(4) of this addendum shall demonstrate that it is in compliance with the requirements~~

~~of Section 3(4)(b)(i), (ii), (iii), (iv), (v), (vi), (vii) and (viii) of this addendum.~~

~~(3) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved pursuant to Section 3(6) of this addendum shall demonstrate that it is in compliance with the requirements of Section 3(6)(b)(i) and (ii) of this addendum.~~

~~(4) An applicant proposing to acquire beds approved pursuant to Section 3(8) of this Addendum shall demonstrate that it is in compliance with the requirements of Section 3(8) of this Addendum.~~

~~(5) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved pursuant to this addendum shall agree to all applicable project delivery requirements set forth in Section 4 of this addendum.~~

APPENDIX A

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS --ADDENDUM FOR SPECIAL POPULATION GROUPS

Michigan nursing home planning areas with a population density of less than 28 individuals per square mile based on 1990 U.S. Census figures.

Planning Area	Population Density per Square Mile
Luce	6.4
Ontonagon	6.8
Schoolcraft	7.1
Baraga	8.8
Alger	9.8
Mackinac	10.4
Iron	11.3
Oscoda	13.8
Alcona	14.9
Lake	15.1
Montmorency	16.2
Gogebic	16.3
Presque Isle	21.0
Missaukee	21.5
Chippewa	21.8
Crawford	21.9
Menominee	23.8
Houghton/Keweenaw	23.9
Kalkaska	24.0

Source: Michigan Department of Management and Budget and the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS -- ADDENDUM FOR NEW DESIGN MODEL PILOT PROGRAM

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds and provides for the establishment of a statewide pilot new design model program.

(2) Except as provided in sections 3 and 4 of this addendum, this addendum supplements, and does not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:
(a) "New design model" means a new nursing home or hospital long-term care unit constructed, renovated, or replaced under the requirements set forth in this addendum.
(b) "Replacement beds" means the applicant proposes to replace an equal or lesser number of beds than currently licensed to the applicant.
(c) "Licensed site" means the geographic location specified on a nursing home or hospital long-term care unit license.

Section 2. Requirements for approval -- purpose of applying for pilot program for a new construction, or replacement/renovation of an existing facility

Sec. 2. A statewide pilot program is established to study the potential benefit of new designs in the new construction, renovation, and/or replacement of existing nursing home and hospital long term-care facilities throughout Michigan. Pilot projects under this addendum shall be new construction, renovation, or replacement projects within the current bed need methodology that conform to the pilot model construction requirements in Section 3.

Section 3. Statewide pilot - new design model for new construction or replacement/renovation facility components

Sec. 3. (1) The pilot will be limited to new construction, renovation, and/or replacement facilities for 4 years, starting on the effective date of this addendum. Applications for a pilot project will not be subject to comparative review.

(2) Projects in the pilot new design model must result in no more than 100 beds per new design model and meet the following design standards:
(a) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled "Minimum Design Standards for Health Care Facilities in Michigan" dated March 1998 and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.
(b) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:
(i) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

~~(ii) electronic nurse call systems shall be required in all facilities;~~
~~(iii) handrails shall be required on both sides of patient corridors; and~~
~~(iv) ceiling heights shall be a minimum of 7 feet 10 inches.~~
~~(c) All new construction, renovation, or replacement facilities approved under this pilot shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.~~
~~(d) The Department may waive construction requirements for pilot projects if authorized by law.~~

~~(3) Pilot projects shall include at least 80% single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the pilot project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.~~

~~(4)(a) The number of beds needed in a planning area as determined by the current bed need methodology will not be changed for this pilot program.~~
~~(b) Projects involving the replacement of existing beds must replace the beds at a location in the replacement zone unless the applicant demonstrates that all of the following are met:~~
~~(i) The proposed licensed site for the replacement beds is in the same planning area, and not within a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including approved projects) within five calendar years prior to the effective date of this addendum,~~
~~(ii) the applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and~~
~~(iii) the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.~~

~~(5) An approved pilot project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.~~

~~(6) The applicant, at the time the application is submitted to the Department, shall demonstrate an agreement to evaluate the new design cooperatively with an appropriate evaluation agent that has been approved by the Office of Services to the Aging (OSA), MDCH and Medical Services Administration (MSA), MDCH. The evaluation will include but is not limited to the following areas: (a) quality of care and quality indicators, (b) client and/or family satisfaction, (c) utilization of drugs, (d) staff recruitment and retention, (e) annual survey reports including complaints, and (f) the impact on capital and operating costs. The evaluation may be expanded to other areas as needed to determine the impact of the new design on delivery of care and quality of life.~~

~~(7) The applicant shall demonstrate, at the time the application is submitted to the Department, all of the following:~~
~~(a) The nursing home or hospital long-term care unit has not been cited by the Department for 1 or more Substandard Quality of Care (SQOC) citations, as defined in the federal regulations, during the 12 months prior to the date an application is submitted to the Department.~~
~~(b) The nursing home or hospital long-term care unit's parent or any subsidiary has taken actions acceptable to the Department to correct, improve, or remedy any condition or concern that resulted in a SQOC citation issued over the past 12-month period in any nursing home or hospital long-term care unit under its parent or any subsidiary.~~

~~Section 4. Pilot project - terms of approval for all applicants seeking approval under Section 3~~

~~Sec. 4. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-~~

~~Term Care Unit Beds.~~

~~(2) In addition to the terms of approval required by the CON Review Standards for nursing Home and Hospital Long-Term Care Unit Beds, an applicant for beds under this addendum shall agree that, if approved, all beds approved pursuant to this addendum shall be dually certified for Medicare and Medicaid. The inability to obtain Medicaid certification of nursing home beds due to the aggregate state-wide limit on the maximum number of Medicaid-certified nursing home beds in Michigan shall not constitute grounds for revocation of the CON if the applicant furnishes to the Department, within one year from the date of CON approval, proof of Medicaid certification or denial of Medicaid certification (based upon the state-wide limit) along with a signed affidavit stating the willingness to certify 100% of the beds subject to CON approval under this pilot program when accepted by Medicaid.~~

~~Section 5. Acquisition of nursing home or hospital long-term care unit beds approved pursuant to this addendum.~~

~~Sec. 5. (1) An applicant proposing to acquire a nursing home or hospital long-term care facility that has been approved as a pilot project pursuant to this addendum shall demonstrate that it is, and will continue to be, in compliance with the requirements of this addendum as a condition of approval.~~

~~(2) An applicant proposing to acquire a nursing home or hospital long-term care facility that has been approved as a pilot project pursuant to this addendum shall agree to all applicable project delivery requirements set forth in Section 4 of this addendum, as a condition of approval.~~

~~(3) An applicant proposing to acquire a nursing home or hospital long-term care facility that has been approved as a pilot project pursuant to this addendum must demonstrate, at the time the application is submitted to the Department, all of the following:~~

~~(a) The applicant or any nursing home or hospital long-term care unit owned or operated by the applicant has not been cited by the Department for 1 or more Substandard Quality of Care (SQOC) citations, as defined in the federal regulations, during the 12 months prior to the date an application is submitted to the Department.~~

~~(b) The applicant's parent or any subsidiary has taken actions acceptable to the Department to correct, improve, or remedy any condition or concern that resulted in a SQOC citation issued over the pas 12-month period in any nursing home or hospital long-term care unit under its parent or any subsidiary.~~

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: February 29, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Nursing Home Quality Measures Workgroup Report

Departmental Task

The Commission received the final report from the Nursing Home and Hospital Long-Term-Care Unit Beds Standard Advisory Committee (NHSAC) at its December 11, 2007 meeting. The NHSAC provided the Commission with its recommendations in draft language for proposed action. Extensive public testimony on the quality measures within the proposed Nursing Home and Hospital Long-Term-Care Unit Beds Standards were heard. The Commission took proposed action on the draft language presented with the NHSAC final report. Additionally, the Commission tasked the Department to convene the Nursing Home Quality Measures Workgroup (Workgroup) with a representative from Michigan Association of Homes and Services for the Aging (MAHSA), Michigan County Medical Care Facilities Council (MCMCFC), Health Care Association of Michigan (HCAM), and Michigan Health and Hospital Association (MHA), along with a balance of non-providers to refine the draft quality measures criteria for consideration at the March 11, 2008 Commission Meeting.

Workgroup Composition

Per Commission direction, the Workgroup had a representative from MAHSA, MCMCFC, HCAM, and MHA. The Department solicited participation from the following non-provider organizations: Area Agency on Aging, Michigan Quality Community Care Council, Michigan Poverty Law Program, and the Office of Services to the Aging. These eight organizations were the core Workgroup, which provided broad statewide prospective. The Workgroup meetings were held utilizing an open format, allowing all attendees to participate in the discussion. This ensured that all interested parties were able to have their ideas and concerns heard.

Quality Measures Proposals

On December 14, 2007, the Department requested that any quality measures proposal to be considered for inclusion in the Standards be submitted electronically via a website link within seven days. Six proposals were received from the following organizations: HCR Manorcare, MCMCFC, HCAM, MAHSA, Sunset Association, and Spectrum Health. Upon receipt, the proposals were posted on the website for public review. The proposals were reviewed by the Department for similarities and became the three discussion item proposals for Workgroup consideration at its meetings.

Workgroup Recommendations

The Workgroup reached a consensus at its third and final meeting in January. The recommendations were modifications to the draft language proposed by the NHSAC. The following are the five recommended modifications:

1. Elimination of the SAC Criteria that looked for two state rule violations showing failure to comply with the state minimum staffing requirements and/or a federal repeat citation.

2. Elimination of the SAC Criteria that looked for repeat citations at the harm or substandard quality of care level issued within the last three years.

3. Recommends that statewide average be calculated from the quarter in which the standard survey was completed in for evaluating the number of citations at level D or above. This gives it a rolling time period.

4. Additional criteria that look for facilities that are listed as a special focus Nursing Home by the Center for Medicare and Medicaid Services.

5. Recommends that common ownership look at out-of-state nursing homes only when an applicant has less than 10 Michigan nursing homes. Thus, if the applicant has 10 or more Michigan nursing homes, then only Michigan homes will be evaluated for the quality measures.

Draft Language of Workgroup Recommendations

The Workgroup modifications recommended were applied to the proposed standards. The document was labeled "For CON Commission Public Hearing on February 6, 2008 with Proposed Amendments." The quality measures can be found for the first time in Section 6, starting on line 306 of that document and are as follows:

> (A) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its Nursing Homes/HLTCUS:

Type of Applicant	Reporting Requirement
Applicant with only Michigan Nursing Homes/HLTCUS	All Michigan Nursing Homes/HLTCUS under common ownership or control
Applicant with 10 or more Michigan Nursing Homes/ HLTCUS and out of state Nursing Homes/HLTCUS	All Michigan Nursing Homes/HLTCUS under common ownership or control
Applicant with fewer than 10 Michigan Nursing Homes/HLTCUS and out of state Nursing Homes/HLTCUS	All Michigan and out of state Nursing Homes/HLTCUS under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a medical assistance provider enrollment and trading partner agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the Nursing Home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus Nursing Home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

The language was appropriately noticed and posted for public comments to be received at the February 6, 2008 Public Hearing. This enables the Commission to take final action on either the proposed language of the NHSAC or the Workgroup at the March 11, 2008 Commission Meeting.

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: March 7, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Review of Public Hearing Testimony on the Proposed Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU) Standards and Recommended Modifications

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." Accordingly, the Department held a Public Hearing to receive testimony on the proposed NH-HLTCU Standards and the proposed Standards with amendments on February 6, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from 17 organizations/individuals and is summarized as follows:

1. AARP Michigan
   - Supports the Standards with proposed amendments, with no additional compromises on the quality measures or modifications.

2. Baraga County Memorial HLTCU
   - Recommends the removal of the requirement that a HLTCU remain within the hospital in Section 8 (1)(f), Section 8 (2)(f), and Section 9 (1)(f).

3. Ciena Healthcare Management, Inc.
   - Generally supports the Standards with proposed amendments, but continues to oppose the utilization of chain survey results to determine facility specific eligibility.
   - Recommends that the quality measures be evaluated with the scheduled review of these Standards in 2010. The review should be completed by a Standard Advisory Committee for impact and additional quality measures.
   - Recommends applying the quality measures on a rolling forward basis. The look back period would start with the effective date of the proposed Standards.
   - Recommends modifying the replacement zone to the planning area without the applicants being subject to comparative review.

4. Citizens for Better Care
   - Supports the Standards with proposed amendments.

5. Consumer Ian Engle
   - Supports the Standards with proposed amendments.

6. Extendicare Healthcare Services (Tendercare, Michigan, Inc.)
   - Supports the Standards with proposed amendments, but continues to be concerned to the utilization of survey results as a quality measure.
   - Recommends elimination of the minimum design standards criteria located in Sections 6(1)(b), 8(1)(d), and 8(2)(d).
   - Recommends elimination of the requirement that plan of corrections must be approved in Sections 6(1)(c), 7(2)(b), 8(1)(e), 8(2)(e), 9(1)(e), and 9(3)(c).
   - Recommends that Sections 6(2)(c) and 8(3)(b) be modified to require 50% single occupancy resident rooms, not 80% of beds in single occupancy resident rooms, as currently proposed.
   - Recommends modification of relocation requirements in Section 7(1)(d) from 7 years to 2 years.
   - Recommends that the comparative review criteria in Section 10(2) and (3) be modified to award points for a commitment to participate in the Medicaid or Medicare Program.
   - Recommends clarification of the term “adjacent private changing room” utilized in Section 10(8).
   - Recommends applying the quality measures on a rolling forward basis. The look back period would start with the effective date of the proposed Standards.
   - Recommends the quality measures criteria look at Level E and above citations, not at Level D.

7. Fair Acres Care Center
   - Recommends additional review of the new bed need numbers. Clarification on how the data was gathered and calculated, with specific concerns about Macomb County.

8. Grandvue Medical Care Facility
   - Recommends elimination of the planning area criteria of the high occupancy provision, located in Section 6(1)(d)(ii)(b).
   - Recommends that the quality measures criteria be applied to the receiving facility within relocation or elimination of the relocation provision at Section 7.
   - Recommends that the minimum staffing level criteria be returned to the quality measures criteria.

9. HCR Manorcare
   - Supports the Standards with proposed amendments, with the assumption that the Commission will immediately address any unintended consequences or irrational outcomes.
   - Recommends additional modification to the comparative review criteria to ensure that new facilities and existing facilities are able to score equally.

- Recommends additional modification of the requirement that plan of corrections must be approved in Sections 6(1)(c), 7(2)(b), 8(1)(e), 8(2)(e), 9(1)(e), and 9(3)(c). Additionally, recommends that the criteria be applied to new design model applicants.
- Recommends elimination of the minimum design standards criteria located in Sections 6(1)(b), 8(1)(d), and 8(2)(d).
- Recommends that Sections 6(2)(c) and 8(3)(b) be returned to original wording of 80% single occupancy resident rooms.
- Recommends modification of the relocation restriction that only allows 50% of the beds per facility to be relocated to 40 beds in Section 7(1)(a).
- Recommends applying the quality measures on a rolling forward basis. The look back period would start with the effective date of the proposed Standards.
- Supports the recommended language changes that HCAM proposed for the minimum design standards criteria and plan of correction criteria.
- Recommends that the implementation date of the new bed need numbers be set for October 1, 2008 to allow applicants time to address the new bed need numbers.
- Recommends additional points be awarded in Section 10(3) for comparative review criteria.

10. Health Care Association of Michigan
    - Supports the Standards with proposed amendments, but continues to be concerned to the utilization of survey results as a quality measure.
    - Recommends that utilization of customer satisfaction is the best indicator of quality of care.
    - Recommends that the implementation date of the new bed need numbers be set six to nine months into the future to allow existing appeals to be resolved.
    - Requests clarification on how the data was gathered and calculated for the new bed need numbers.
    - Recommends elimination of the minimum design standards criteria located in Sections 6(1)(b), 8(1)(d), and 8(2)(d).
    - Recommends modification of the requirement that plan of corrections must be approved, suggest that the plans must be submitted in Sections 6(1)(c), 7(2)(b), 8(1)(e), 8(2)(e), 9(1)(e), and 9(3)(c).
    - Recommends that Sections 6(2)(c) and 8(3)(b) be modified to require 50% of the beds be located in single occupancy resident rooms, not 80% as currently proposed.
    - Recommends modification of relocation requirements in Section 7(1)(d) from 7 years to 2 years.
    - Recommends that the comparative review criteria in Section 10(2) and (3) be modified to also award points for a commitment to participate in the Medicaid or Medicare Program for new providers.
    - Recommends clarification of the term “adjacent private changing room” utilized in Section 10(8).
    - Recommends modifying the replacement zone to the planning area without the applicants being subject to comparative review.

11. Lutheran Home of Michigan, Inc.
    - Recommends elimination of the planning area criteria of the high occupancy provision, located in Section 6(1)(d)(ii)(b).
    - Opposes relocation within the Standards and recommends elimination of Section 7.

12. MediLodge Group
    - Recommends additional review of the bed need methodology to take into account assisted living, home health care, adult foster care, and home for the aged.
    - Recommends that the implementation date of the new bed need numbers be set to take into account comparative reviews.
    - Recommends that Sections 6(2)(c) and 8(3)(b) be modified to require 50% of the beds be located in single occupancy resident rooms, not 80% as currently proposed.

13. Michigan Association of Homes and Services to the Aging
    - Supports the Standards with proposed amendments.
    - Recommends elimination of the planning area criteria of the high occupancy provision, location at Section 6(1)(d)(ii)(b).
    - Recommends that Religious Beds be maintained as a current category under Section 3(1)(a) of the Addendum for Special Population Groups.
    - Opposes relocation within the Standards and recommends elimination of Section 7.
    - Recommends that the acquisition of an existing facility not require that the facility be operating. The acquisition would be allowed until all avenues of appeal have been exhausted for the revocation of the license.
    - Recommends that the modification to the comparative review criteria in Section 10(2) and (3) be removed and the language returned to the original language.

14. Michigan County Medical Care Facilities Council
    - Supports the Standards with proposed amendments.
    - Recommends elimination of the planning area criteria of the high occupancy provision, located in Section 6(1)(d)(ii)(b).

15. Michigan Poverty Law Program
    - Supports the Standards with proposed amendments.
    - Recommends immediate implementation of the quality measures.
    - Recommends no further revision of the Standards until the scheduled review in 2010.

16. Michigan State Long Term Care Ombudsman
    - Supports the Standards with proposed amendments.
    - Recommends immediate implementation of the quality measures.

17. Spectrum Health
    - Opposes the approval of either set of Standards.
    - Recommends the quality measures criteria look at Level E and above citations, not at Level D.
    - Recommends additional evaluation of the common ownership requirements to increase above the 14% currently proposed.
    - Recommends the high occupancy provisions contained in Section 6(1)(d)(ii)(a) be modified to a requirement of 90% for two years and elimination of the planning area criteria at Section 6(1)(d)(ii)(b).

Staff Analysis and Recommendations

The public hearing testimony overwhelmingly supports utilization of the Nursing Home and Hospital Long-Term-Care Unit Beds Standards with Proposed Amendments. Accordingly, the Standards with proposed amendments are recommended for final action. It is recommended that the Standards be approved with a set effective date to coordinate with the effective date of the new bed need numbers. It is recommended that the effective date be June 2, 2008.

The following outlines any recommended modifications resulting from public hearing testimony on the Standards with proposed amendments:

1. Bed Need Numbers Implementation Date [Section 4(4)]
   Testimony from three organizations recommended setting an implementation date for the new bed need numbers to a date into the future, such as October 1, 2008, to allow applicants to prepare for the change. Pursuant Section 4(4), "The effective date of the bed need numbers shall be established by the Commission." The next comparative review window date is June 2, 2008, and it is recommended that this should be the effective date of the bed need numbers.

2. High Occupancy [Section 6(1)(d)(ii)]
   Testimony from five organizations recommended modification to the high occupancy provisions, which require meeting two criteria. The facility must have an occupancy rate of 97% for the most recent 12 quarters. Secondly, all facilities within the planning area must also meet the 97% occupancy rate for 12 quarters.

   The Nursing Home Standards Advisory Committee (NHSAC) evaluated this issue as part of the charge and recommended no action. The Department supplied occupancy rates on 433 facilities. Of those facilities, ten met the 97% for 12 quarters criteria, while no planning areas met the criteria. Thus, no facility would be eligible for high occupancy under the current criteria.

   Given that the current criteria are essentially non-functioning and inconsistent with other CON Standards, modification would seem appropriate. The Standards should be modified by elimination of the planning area criteria and modification of the facility criteria to 97% average occupancy for 12 quarters. This would make the high occupancy criteria obtainable and similar to other Standards.

3. Quality Measures

A. Utilization of Level D Citations

Testimony from two organizations recommended utilizing level E as the starting point for evaluating two times the statewide average for the quality measures criteria. Both the NHSAC and the Nursing Home Quality Measures Workgroup (Workgroup) spent extensive time on this issue and recommended level D as the appropriate starting point. No modification to the Standards should be taken.

B. Implementation

Testimony from two organizations recommended applying the quality measures from the effective date of the Standards going forward. Thus, if the Standards took effect on May 1, 2008, the Department would only be able to look at citations from that date forward. This essentially keeps the quality measures from fully functioning until three years after the effective date. Additionally, two organizations recommended immediate implementation. No modification to the Standards is recommended, and the quality measures should be implemented upon the effective date of the Standards.

C. Applicability to Relocation (Section 7)

Testimony from one organization recommended that the quality measures be applied to the receiving facility at Section 7(2). Inclusion of the quality measures would ensure that a poorly performing facility is not allowed to expand through relocation of beds. The Standards should be modified to include the quality measures criteria within Section 7(2) for the receiving applicant in relocation.

4. Comparative Review (Section 10)

A. Medicaid and Medicare Criteria [Section 10(2) and (3)]

Testimony from four organizations requested modification to the Medicaid and Medicare criteria to ensure equal treatment of the applicants for new and existing facilities by allowing applicants for new facilities to be allowed to project their participation in Medicaid and Medicare. Allowing an applicant to project is how the criteria previously worked. The Standards should be modified to allow projections for new facilities, while retaining the requirement that existing nursing homes must utilize historical data.

B. Adjacent Private Changing Room [Section 10(8)]

Testimony from two organizations recommends further clarification of the term adjacent private changing room utilized in the comparative review criteria. This term is not clearly defined within Section 2 of the Standards. The Standards should be modified by adding a clarifying statement with use of this term in Section 10(8).

5. Relocation (Section 7)
Testimony from two organizations recommended elimination of the relocation provision within the Standards. While two other organizations recommended modification of the frequency that a facility could relocate beds from seven years to two years in Section 7(1)(d). Another organization recommended modifying the relocation restriction that only allows 50% of the beds per facility to 40 beds in Section 7(1)(a). This is the first time that relocation has been allowed within the Standards and will allow under-utilized facilities to transfer beds to another facility within the planning area. No modification to the Standards is recommended.

6. Minimum Design Standards Criteria [Sections 6(1)(b), 8(1)(d), and 8(2)(d)]
Testimony from three organizations recommends elimination of the minimum design standard criteria. The applicant is required to certify that they have reviewed and that the proposed project complies with the minimum design standards to meet this criteria. Comparative review applications are not allowed to amend their projects or project costs, pursuant to Rule 325.9215(1). Thus, this provision ensures that the applicant has determined that their project will not need major plan or cost modification upon submission of the blueprints for review. No modification to the Standards is recommended.

7. Plan of Correction Criteria [Sections 6(1)(c), 7(2)(b), 8(1)(e), 8(2)(e), 9(1)(e), and 9(3)(c)]
Testimony from three organizations to modify the plan of correction criteria to not require that the plan be approved and that the plan only has to be submitted, if it is due. The plan of correction language within the currently effective standards, located at Section 7(2), requires that plans be submitted and approved. The current language was updated with Department references and applied to the appropriate sections. No modification to the Standards is recommended.

Testimony from one organization noted that the plan of correction criteria was not applied to applicants applying under new model design. This was an oversight, and the criteria should be applied to applicants for new model design. The Standards should be modified to include the plan of correction criteria within the new model design sections.

8. HLTCU criteria [Sections 8(1)(f), 8(2)(f), and 9(1)(f)]
Testimony from one organization requested the elimination of the requirement that an HLTCU remain with the hospital located at Sections 8(1)(f), 8(2)(f), and 9(1)(f). This language was originally recommended by the Department. Unfortunately, the language did not reach its intended goal and ended up being counter productive. The Standards should be modified by eliminating the criteria.

9. New Design Model – Single Occupancy Rooms/Beds Criteria [Sections 6(2)(c) and 8(3)(b)]
   Testimony from three organizations requested modification of the single occupancy room/beds criteria in Sections 6(2)(c) and 8(3)(b). The NHSAC added the words "of the beds in" before single occupancy resident rooms. The addition of these words made the criteria more difficult to obtain and was not the intent of the modification. It is recommended that "of the beds in" be removed from Sections 6(2)(c) and 8(3)(b).

Summary of Recommend Modifications to the Standards with Proposed Amendments

- Inclusion of a clarifying language with the use of adjacent private changing room in Section 10(8).
- Removing the HLTCU criteria at Sections 8(1)(f), 8(2)(f), and 9(1)(f).
- Modification of the high occupancy criteria at 6(1)(d)(ii) by modifying the facility criteria to 97% average occupancy for 12 quarters and eliminating the planning area requirement.
- Inclusion of the plan of correction criteria in new model design at Sections 6(2), 6(3), and 9(2).
- Inclusion of the quality measures criteria within for the receiving facility in relocation at Section 7(2).
- Modification of Medicaid and Medicare criteria within comparative review to allow projection of participation levels for new applications in Sections 10(2) and (3).
- Removing the words "of the beds in" from Sections 6(2)(c) and 8(3)(b).

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, ~~9,~~ and 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 9, AS APPLICABLE, IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

(~~5~~6) The Department shall use Section 10, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(c) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(d) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(e) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(f) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(g) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(h) “Dedicated endoscopy or cystoscopy operating room” means a room used exclusively for endoscopy or cystoscopy cases.

(i) "Department" means the Michigan Department of Community Health (MDCH).

(j) “Emergency Room” means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(k) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

(l) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(m) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a certified ASC.

(n) "Expand a surgical service" means the addition of one or more operating rooms at an existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a non-dedicated OR.

(o) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site.

(p) "Hospital" means a health facility licensed under Part 215 of the Code.

(q) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(r) "Initiate a surgical service" means to begin operation of a surgical facility at a site that has not offered surgical services within the 12-month period immediately preceding the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(s) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital 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 site as authorized by licensure.

(t) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(u) "Metropolitan statistical area county” means a county located in a metropolitan statistical area as that term is defined under the “standards for defining metropolitan and micropolitan statistical areas” by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(v) "Micropolitan statistical area county” means a county located in a micropolitan statistical area as that term is defined under the “standards for defining metropolitan and micropolitan statistical areas” by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(w) "Offer" means to perform surgical services.

(x) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.

(y) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(z) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(aa) “Procedure room” means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor.

(bb) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services within the relocation zone.

(cc) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or micropolitan statistical area county.

(dd) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(ee) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. This term also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term does not include the renovation of an existing surgical service or one or more operating rooms.

(ff) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(gg) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(hh) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(jj) "Surgical service" means performing surgery in a surgical facility.

(kk) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(ll) “Verifiable data” means surgical data (cases and/or hours) from the most recent Annual Survey or more recent data that can be validated by the Department.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. Compliance with CON minimum volume requirements established by these standards shall be determined based on the average number of surgical cases, hours of use, or both, per operating room of the surgical service as permitted by these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), and (iii).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.

(3) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of surgical cases projected under subsection (1).

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:
(i) 1,216 surgical cases per year per operating room for which verifiable data is available to the Department, or
(ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or
(iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:
(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to 438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00 OR), or
(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:
(A) the number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases would equate to 438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00 OR.)
(b) All proposed operating rooms are projected to perform an average of at least:
(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or
(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or
(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:
(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or
(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:
(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:
(a) The applicant has two, three, or four ORs at the licensed hospital.
(b) All existing operating rooms have performed an average of at least:
(i) 979 surgical cases per year per operating room for which verifiable data is available to the Department, or
(ii) 1,400 hours of use per year per operating room for which verifiable data is available to the Department.
(c) All proposed operating rooms are projected to perform an average of at least:
(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or
(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has only one operating room.

(4) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of surgical cases, or hours of use, projected under subsection (1).

Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or more operating rooms

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(b) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter,or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan statistical area county and has one or two operating rooms.

(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall submit notification to the Department on a form provided by the Department. An applicant under this subsection shall not be required to comply with subsections (1) and (2).

Section 7. Requirements for approval for applicants proposing to relocate an existing surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate an existing surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be relocated have performed an average of at least:

(a) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or,

(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(4) All operating rooms, existing and relocated, are projected to perform an average of at least:
(a) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or
(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or
(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:
(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.) or
(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:
(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(5) SUBSECTIONS (3) AND (4) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES RELOCATING ONE OR TWO OPERATING ROOMS WITHIN THE RELOCATION ZONE, IF THE SURGICAL FACILITY IS LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

(~~5~~6) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:
(a) The applicant has three, four, or five ORs at the licensed hospital.
(b) All existing operating rooms have performed an average of at least:
(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or
(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.
(c) All operating rooms, existing and relocated, are projected to perform an average of at least:
(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or
(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(~~6~~7) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of surgical cases, or hours of use, projected under subsection (4) AND (6).

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:
(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, on or after January 27, 1996, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

(6) Subsection (5) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

Section 9. Requirements for approval -- all applicants

Sec. 9. An applicant shall provide evidence of participation in Medicaid or in Medicaid managed care products or attestation that the applicant has been unable to contract at current Medicaid rates at the time the application is submitted to the Department. By providing a signed affidavit, an applicant that is an ASC or FSOF shall demonstrate a willingness to participate when accepted by Medicaid. An applicant that is initiating a new service or 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.

Section 10. Project delivery requirements -- terms of approval for all applicants

Sec. 10. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following terms of approval, as applicable:

(i) The approved services and/or operating rooms shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The designation of ORs as defined by the standards shall not be changed without prior notification to the Department.

(iii) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) not deny surgical services to any individual based on ability to pay or source of payment;

(B) provide surgical services to any individual based on the clinical indications of need for the service.

(C) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iv) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(v) The applicant shall provide the Department with a notice stating the first date on which the service became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(f) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter or attest that the applicant has been unable to contract with Medicaid managed care products at current Medicaid rates.

(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~ AGREED TO BY the applicant or its authorized agent.

Section 11. Documentation of projections

Sec. 11. (1) An applicant required to project volumes of service ~~under the applicable sections of these standards~~ shall specify how the volume projections were developed and shall include only those surgical

cases performed in an OR. ~~This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.~~ (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 COMMITMENT, PURSUANT TO SUBSECTION 2(D).

(2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will continue to be in compliance with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 12. Effect on prior CON review standards; comparative reviews

Sec. 12. (1) These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~December 13, 2005~~ MARCH 21, 2006 and effective on ~~January 30, 2006~~ JUNE 5, 2006.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS FOR SURGICAL SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

Certificate of Need (CON)

Intra-operative Magnetic Resonance Imaging (iMRI)

An Abstract

Michigan Department of Community Health
Health Policy, Regulation and Professions Administration
Prepared for the March 11, 2008 CON Commission Meeting

Introduction

The Commission charged the Department, at its December 11, 2007 meeting, with providing an abstract to address the Intra-operative Magnetic Resonance Imaging (iMRI) issue.

The iMRI system is both a diagnostic and intra-operative tool for radiologists and surgeons. The main goal of the system is to provide a valuable adjunct to standard neurosurgical care without adversely affecting surgical, anesthetic, and nursing management. iMRI allows surgeons to better identify tumors and lesions, differentiate diseased and healthy tissue, and account for motion.

The types of brain surgery for which iMRI is most useful are:

- Tumors located close to areas of important brain function
- Pituitary tumors and other masses along the skull base
- Epilepsy surgery
- Functional neurosurgery targeting precise locations – e.g., placement of electrodes for deep brain stimulation to treat movement disorders.

In Michigan, Harper University Hospital has been operating an iMRI unit, Polestar N-10 0.15T, exclusively for research purposes since April 2003 (See Appendix A).

Work Group Discussion

On January 24, 2008, the Department convened a workgroup consisting of providers, experts, and consumers with Michael A. Sandler, MD, as the liaison to the Certificate of Need (CON) Commission. There were approximately 24 people in attendance (See Appendix B). This meeting was primarily to gather information regarding the use of iMRIs.

A white paper titled “Response to request for information from Michigan Department of Community Health - For the Intra-Operative MRI Certificate of Need Commission Report, January 24, 2008” was presented to the workgroup by the experts from The University of Michigan, Department of Neurosurgery (See Appendix C).

The discussion focused on the costs and benefits of IMRIs. According to the experts who were present at the meeting, the benefits outweighed the costs and they strongly advocated that there was a need for IMRIs in the State of Michigan and that it would improve the quality of care and reduces the need for and risks of additional operations for both adult and pediatric patients who undergo neurosurgery.

There was also some discussion on volume requirements. The current CON standards for MRI Services require an applicant proposing to expand an existing fixed MRI service to demonstrate that its existing fixed MRI units to perform at least an average of 11,000 adjusted procedures for each fixed unit. Since craniotomy volumes are low, and can be used only for inpatients, should variance in volumes be made in the Standards for facilities acquiring iMRIs? Use of IMRIs as diagnostic magnets for outpatients is unlikely because there are sterile corridor[1] issues related to the operating suites.

[1] "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

Survey of other states:

A survey was conducted of other states. Of the 14 responses received, Massachusetts and Virginia are the two states that have and regulate iMRIs. Massachusetts has two (2) iMRIs located in the academic centers and Virginia has one (1) iMRI located in a community hospital. In both cases, the determination of need was made on a case by case basis. The states that responded to our survey were Alaska, Florida, Illinois, Massachusetts, Mississippi, Missouri, Nebraska, New Jersey, Oregon, Ohio, Tennessee, Vermont, Virginia and Washington.

Costs:

Considering the complexity of MRI, which uses a powerful magnetic field and radio waves to create cross-sectional images of the body, bringing the technology into a surgical environment requires careful thought and planning. A single system costs $2-3 million. The operating room design used for iMRIs differs from the conventional operating room. This magnet is ceiling mounted on track beams attached to the building support walls to glide in and out of the operating room~~,~~ and can be used for diagnostic imaging when the magnet is not being utilized for surgical procedures. Significant investment costs are associated with iMRI, which may include system, construction and installation costs, including structural reinforcements, RF shielding, acoustic shielding, personnel costs, acquiring MR-compatible surgical supplies and monitoring equipment or testing existing materials for MR compatibility. The projected cost for both iMRI and operating room construction can add up to anywhere from $6 to $9 million.

Benefits:

- Reduction in lengths of stay
- Reduction of repeat resection rates
- Reduction in hospital charges and costs
- Reduction of complications
- Improvements in surgical outcomes
- Helps clinician confidence of all surgeries performed

Drawbacks:

- iMRI systems can be very expensive, and there is no additional reimbursement for procedures under iMRI.
- iMRI can add up to 90 minutes to operating time depending on type of scans used.
- There is a lack of long-term data on iMRIs that raises questions about durability of clinical outcomes.

Conclusion:

The intraoperative use of MRI imaging in neurosurgery has just started. Applications and protocols for iMRI are still in development. Current iMRI applications are dominated by neurosurgery and best suited for specialized neurosurgery facilities that focus on very complex adult cancers or large pediatric hospitals.

Appendix A

Level 1, Level II and Level III Trauma Hospitals

Year 2005 data related to brain surgery extracted from MIDB for Selected DRG Codes[2]:

Level I Hospitals:					
HSA	**Hospital**	**City**	**Total # of Patients**	**% of Patients from HSA**	
1	Beaumont	Royal Oak	819	92%	1
1	Childrens	Detroit	773	85.9%	1
1	Detroit Receiving	Detroit	113	92%	1
1	Henry Ford	Detroit	699	87.8%	1
1	U of M	Ann Arbor	991	51.6%	1
2	Sparrow	Lansing	372	79.8%	2
3	Borgess	Kalamazoo	422	95.7%	3
3	Bronson	Kalamazoo	207	96.1 %	3
4	Spectrum Health	Grand Rapids	751	89.1%	4
5	Hurley Medical	Flint	113	84.1%	5
Level II Hospitals:					
1	St. Joseph Mercy	Ann Arbor	328	78.4	1
4	St. Mary's Hlth Care	Grand Rapids	177	88.7%	4
5	Genesys Health	Grand Blanc	193	88%	5
5	McLaren General	Flint	282	90.4%	5
Level III Hospital:					
4	Holland	Holland	23	95.6%	4
Other:					
1	Harper Hospital[3]	Detroit	588	83%	1
7	Munson Medical	Traverse City	284	88%	7
8	Marquette General	Marquette	238	99.6%	8

[2] 001(Craniotomy Age>17 w cc),002(Craniotomy Age>17 w/o cc),003(Craniotomy Age 0-17),007(Peripheral & Cranial nerve & other nerv syst proc w cc),008(Peripheral & Cranial nerve & other nerv syst proc w/o cc),049(Major Head & Neck Procedures),286(Adrenal & Pituitary Procedures),484(Craniotomy for multiple significant trauma),533(Extracranial Procedures w cc) and 534(Extracranial Procedures w/o cc)

[3] This hospital has been operating an intra-operative MRI unit exclusively for research purposes since April 2003.

Appendix B

January 24, 2008 iMRI Work Group Participants:

Bradford Betz	Spectrum Health
Brenda Rogers	Michigan Department of Community Health
Cormac Maher, MD	University of Michigan
Dale Downes	Mid Michigan MRI
Dennis McCafferty	Economic Alliance of Michigan
Donald Tomford	University of Michigan
Elizabeth Palazzolo	Henry Ford Health System
Ellen Schrader	Munson Medical Center
Helen Osterwald	S.W. Michigan Imaging
Irma Lopez	Michigan Department of Community Health
Lakshmi Amarnath	Michigan Department of Community Health
Larry Genzink	Spectrum Health
Larry Horwitz	Economic Alliance of Michigan
Melissa Cupp	Wiener Associates
Michael Sandler,MD	Henry Ford/CON Commissioner
Monica Harrison	Oakwood
Oren Sagher, MD	University of Michigan
Penny Crissman	Crittenton Hospital
Robert Meeker	Spectrum Health
Sallie Flanders	Michigan Department of Community Health
Steven Szelag	University of Michigan
Teresa Jacobs,MD	University of Michigan
Walter Wheeler	Walter Wheeler Associates

Appendix C

Response to Request for Information from Michigan Department of Community Health
For the Intra-Operative MRI Certificate Need Commission Report
January 24, 2008

Executive Summary

Intraoperative MRI is an emerging technology that promises to improve the quality of patient care by improving the accuracy of surgical procedures, with improved patient outcomes and reduced morbidity. An MRI performed during the midst of a surgical procedure provides the best available anatomic information to a surgeon and is becoming the standard of care at top ranked medical centers in the United States and Europe. The current Michigan CON regulations governing diagnostic MRI are not designed for intraoperative MRI use and are presently preventing adoption of this technology long after it has been accepted by other states. Michigan hospitals are already behind their peer institutions in this regard. Intraoperative MRI requires a high capital outlay. For neurosurgical settings, this can be recouped from reduced cost of reoperation and reduced cost of care for rehabilitation after neurological injury. Additional cost recovery is possible in some applications by combining intraoperative and diagnostic MRI scanning on the same machine. Potential CON regulatory solutions include classification of intraoperative MRI as an operative tool for use in an operating environment, or developing a mixed use CON MRI requirement based primarily on intraoperative use. Timeliness in this process is important to containing costs as several institutions are currently building facilities and installation during initial construction is significantly less expensive than retrofitting.

Disclosures: The authors have no proprietary interest in any company providing intraoperative MRI technology, other that as a holders of institutional mutual funds that may periodically hold stock such companies. Similarly, the authors have no contractual or consulting relationship with any company providing intraoperative MRI technology, and meet the University of Michigan requirements for “no interest to disclose” on this topic. The authors are Neurosurgeons and faculty members of the University of Michigan Dept of Neurosurgery.

Introduction – What is Intraoperative MRI?

“Intra-operative” and “interventional” MRI describes the integrated use of MRI technology during surgical and interventional procedures. Specifically, the term implies the conduct of MRI imaging during a surgical or interventional procedure. Intra-operative MRI thus refers to the physical presence of an MR unit in an operative or procedurally intensive health care environment. MRI imaging generally provides the greatest ability to assess non-bony tissues of the body. MRI imaging provides two and three-dimensional imaging of the anatomic structures that are critical to the performance of surgical or interventional procedures. While diagnostic MRI has been available for several decades, intraoperative MRI is an emerging technology whose full potential is yet to be realized. There is however, a growing body of experience both in the United States and Europe with the use of this technology suggesting that it improves patient outcomes.

Rationale

MRI is currently the state-of-the-art for non-invasive imaging of body structures. In many cases, the imaging available from MRI is superior even to direct surgical visualization of the anatomic structures involved. For example, MRI offers the best visualization of most brain tumors. Currently, the most common practice in the surgical management of brain tumors involves obtaining an MRI pre-operatively to document the location and extent of a brain tumor. A surgical procedure is then performed to remove the lesion and a post-operative MRI is then obtained to document the extent of resection. In many cases, the patient's outcome is strongly dependent on the extent to which a surgical removal of the tumor is complete. Intra-operatively, a surgeon is dependent upon the anatomic, visual and tactile characteristics of a tumor to determine which tissues to remove and which must be left behind to avoid neurological injury. However, in many cases, a brain tumor may not appear or feel very different from adjacent functioning brain tissue. While the MRI study obtained before a surgical procedure is a guide, changes in anatomy from the surgical exposure and from the initial steps of the tumor removal distort the anatomy such that the pre-operative MRI is often no longer particularly representative of the operative situation. In these cases, it is not uncommon for a residual tumor to be present despite a surgeon's best efforts. Currently, the operative procedure must be concluded in its entirety and the patient be taken out of the operating environment for an MRI scan. Residual tumor, if present, then requires a second surgical procedure, usually at a later time for further management. This exposes the patient to the additional risks of a second anesthetic, and/or increased infection risks from re-operating through a fresh surgical site. An MRI scan, if obtained while the surgical procedure was in progress, would allow for immediate recognition of additional tumor and subsequent removal during the same operation. In addition, intraoperative MRI significantly improves the ability to recognize normal tissues and avoid removing them. Again with respect to brain tumor resection, surgical invasion into functional areas thought incorrectly to be abnormal, produces morbidity to the patient and potential permanent loss of neurologic function. The ability to provide high quality intra-operative imaging of the tumor and associated anatomy could significantly reduce the likelihood of damage to functional structures adjacent to pathologic lesions. While other potential intraoperative technologies, specifically computed tomography and ultrasound, allow visualization of the brain neither of these modalities can compare to MRI in terms of tissue differentiation, so critical for improving operative safety.

The principles described above apply to a wide variety of neurosurgical procedures involving the brain and spinal cord, including the surgical management of epilepsy, cerebral vascular malformations, spinal cord & column tumors. In addition, other neurosurgical applications include the precise placement of neuro-stimulatory electrodes into various nuclei of the brain for the treatment of movement disorders such as Parkinson's disease and Dystonia. In each of these cases, real time intra -procedural imaging offers a clear opportunity for improved patient outcomes and reduced procedural morbidity.

A number of publications in the medical literature demonstrate the value of this technology. In a study of 137 pts undergoing brain tumor resection with intraoperative MRI guidance, 40% had additional tumor resected as a result of the MRI. The incidence of permanent neurological injury was only 3%, very low for the type of procedures performed.[1] Several other studies suggest that

intra operative MRI leads to additional tumor resection in 25-70% of cases. [2-6,10,15] Other studies support its use in epilepsy surgery, vascular neurosurgery and complex spine & skull base surgery.[7-8,11-14] In one case-controlled study, patients undergoing glioblastoma resection with intraoperative MRI achieved complete radiographic resection in 31% vs 19% for controls operated without intraoperative MRI. Radical resection was associated with a significantly longer median survival.[9]

Intra-operative MRI technology has also been used for a variety of body systems including tissue biopsy throughout the body. It has been used to direct ablation treatments where it can directly monitor the intentional tissue injury during the procedure.[16] Finally, MRI technology allows for visualization of the vascular system and interventional MRI angiographic procedures such as vascular stent placement and intra-arterial administration of medications such as chemotherapy.

In all these applications, MRI offers advantages over conventional techniques both in eliminating the effect of ionizing radiation for the patient and physician as well as improved tissue visualization. This is of particular relevance in the pediatric area where ionizing radiation has a clearly demonstrated adverse impact on neurocognitive outcomes. [17]

Intraoperative MRI is an emerging technology, much as diagnostic MRI was two decades ago. Given that MRI is the best available tool for imaging of soft tissues, it is very likely that additional applications will become clear as the technology become more widely available.

Platforms

A number of different intra-operative MRI platforms are currently available. These applications are currently functioning in a variety of institutions both in the United States and Europe. Portable, Low Field Strength (0.15 - 0.3 telsa) devices are currently marketed by Medtronics corporation and others. These devices can be moved into an operating environment when needed, but offer more limited image quality. Typically there are slightly larger than a standard operating table. The MRI pivots up from below the operating table when needed. The cost of these devices is lower than for High Field strength installations but the image quality of these units is below that of standard diagnostic MRI. High Field strength intraoperative MRI machines resemble diagnostic MRI machines in size and weight. These units (1.5 or 3.0 Tesla) are marketed by Siemens, General Electric, Hitachi, IMRIS and other vendors as either fixed or track mounted units. These provide high quality images but require a standard magnetically shielded environment, and building infrastructure to support their substantial weight. Among standard field strength units, the mechanisms in which the patient and magnet are brought together differ, with some vendors moving the patient into the magnet on a motorized table, and other vendors moving the magnet around the patient using a motorized gantry. As noted above, because of the high magnet field strength involved in MRI technology, the operative environment must be significantly modified to allow for successful implementation of this technology. In most applications currently in use, the MRI device is used specifically and exclusively for intra-operative or interventional radiographic procedures. However, several applications have allowed for combined use of both intraoperative and diagnostic capabilities.

Given the high cost of these devices, mixed diagnostic and intraoperative use will be attractive to some institutions seeking to offset the high capital costs with additional utilization.

A partial list of vendors and currently in-place intraoperative MRI sites is provided at the end of this document. Many of these companies and health care sites already have several years of experience with their devices and can offer additional information and expertise to the committee. In addition, the states of Missouri, North Carolina, South Carolina, Tennessee and Virginia all have CON statutes and have intraoperative MRI installations within their borders.

Beneficiaries / Stakeholders

Patients in the State of Michigan undergoing MR based procedures will benefit substantially from this technology with increased likelihood of procedural success and reduce complication rates. Health care providers stand to gain by this technology as it offers unique opportunities to advance the various disciplines that utilize the technologies. Clearly hospital institutions face challenges related to this technology due to its significant expense and uncertain cost benefit ratios in pure financial terms. Insurance providers and other payers face undetermined impact in terms of cost of procedures performed under these conditions.

Certificate of Need Priorities

Access

Currently, residents of the state of Michigan must travel outside the state to obtain care for this type of technology as no institution possesses this technology. As noted in the appendix, Michigan is one of the few states in the region without intraoperative MRI capabilities. Kentucky, Illinois, Minnesota, Missouri, Ohio and Wisconsin and all have either adult and/or pediatric hospitals with intraoperative MRI. Many of these institutions have low-field strength MRI capabilities.

Intraoperative MRI will always have a lower utilization on a case basis than a dedicated diagnostic MRI. The long duration of surgical procedures using intraoperative MRI means that the current State of Michigan CON case volume requirements for MRI installations far exceed what is ever likely to be practical with any intraoperative MRI, even in a combined intraoperative/diagnostic installation. These regulations in part, account for the lack of intraoperative MRI capabilities within the state. If intraoperative MRI is to become available in Michigan a new regulatory CON category or exception will need to be created.

Quality of Care

As indicated above, there is substantial evidence, that intraoperative MRI improves the quality of care for adult and pediatric patients with a variety of diagnoses. With regard to the best studied indication of brain tumor resection, it appears to significantly increase the extent of surgical resections, translating into improved survival, with no increase in neurological deficits from the more aggressive resections performed. From a patient perspective there appear to be few downside risks. Intraoperative MRI does require vigilance with respect to the potential for injury from certain metal objects in the high magnetic field environment, however, to date this has been successful and there are no reported injuries specifically related to an intraoperative MRI.

Balancing Cost

Intraoperative MRI is extremely expensive. Low field strength solutions cost $2.5 million in capital cost and perhaps require 5-10% of that per year to operate. High field strength solutions cost $5 - $7 million, with similar yearly operating costs to a fixed diagnostic MRI unit. Some cost savings will occur due to a reduction in repeat operative procedures and reduced length of stay. Additional cost savings may accrue as the cost of caring for post-operative surgical morbidity is reduced. One study from the University of Minnesota noted that for the DRG's most closely related to brain tumor resection, intraoperative MRI use was associated with a 55% reduction in length of stay from 8.2 days to 3.7 days and was associated with lower costs and charges.[18] Unfortunately no study providing a comparative measure such as the cost of a quality adjusted life year (QALY) is available to date. We expect in our initial proposed installation of the device at the new Mott Children's hospital to be used in perhaps 50 cases per year for brain tumor resections. For calculation purposes, if one postulates an intraoperative case volume of 100 case per year, to account for the likely growth in indications for its use as the technology and our experience matures, and a 10 year lifespan for the capital depreciation, and a 5% operating cost per year, the calculated costs per scan are $3,750 and $9,000 for low and high field strength scans respectively. The rough cost of a repeat craniotomy for tumor resection including both professional and hospital costs is roughly $14,000-$20,000 for comparison.

For brain tumor patients, the current standard of care calls for an immediate post-resection diagnostic MRI. With a high field strength intraoperative MRI solution, this study would be performed in intraoperative MRI with the patient still anesthetized, freeing institutional diagnostic MRI machines for other patients. As noted above high field strength solutions offer the opportunity for additional cost recovery with routine diagnostic MRI scanning when the device is not in use for intraoperative purposes. While potentially attractive at an institutional level, we acknowledge that this introduces additional regulatory complexities, and could potentially lead to abuse of the CON process for diagnostic MRIs. Realistically this would only be a concern for high field strength applications. To close this potential loophole, we propose that an intraoperative MRI be defined as an MRI either physically attached to (for high field strength applications), or predominantly for use in (for low field strength applications) a CON approved Operating Room environment. Proliferation of the technology could then be controlled in part via the existing CON statues governing Operating Room construction. Because of the improved economies of combined intraoperative and diagnostic use, regulatory language that eliminates the possibility of diagnostic capabilities would be in our view, undesirable. Mixed use settings could be reasonably regulated either with a reduced case volume CON requirement for the diagnostic use or tying CON approval for diagnostic use to sufficient intraoperative MRI case volume to prevent the application of an intraoperative MRI CON standard to an MRI intended primarily for diagnostic use.

Timeliness

Developing a process for intraoperative MRI regulation is of immediate importance to the commission because a number of institutions throughout the state are currently in the process of building new facilities. The cost of integrating this technology into an existing facility is

significantly greater than the cost of designing and installing the technology during primary building construction. It is estimated that retrofitting an existing environment can increase costs between 30 and 60% over installation at initial building construction. In addition, the use of intraoperative MRI is increasing nationwide and if Michigan institutions are prevented from implementing this technology, they will fall notably behind other peer facilities regionally and nationally, limiting the ability to provide both state-of-the-art care and conduct medical research. It is already clinical experience that patients are aware of this technology and are making choices as to where to receive health care based on availability of technology if they have the means to do so. Clinicians are motivated to seek this technology on the basis of a desire to improve outcomes for patients under their care. Attracting and retaining the best and brightest surgeons and radiologist requires a commitment to such state of the art facilities.

Respectfully submitted,

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Appendix C

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Appendix C

Hospital facilities with intraoperative MRI suites

MIDWEST REGION

Akron Children's Hospital, Akron, OH
Columbus Children's Hospital, Columbus, OH
Mayo Clinic, Rochester, MN
Cleveland Clinic
Lutheran General Children's Hospital (Chicago)
Barnes/St. Louis Children's (installation in progress)
Rainbow Babies (Cleveland)
St. Louis University Hospital
Abbot Northwestern (Minneapolis)
Sacred Heart Hospital (Eau Claire, Wisconin)
University of Minnesota
St. Joseph's Hospital (Marshfield, Wisconsin)
Kosair Children's Hospital (Indiana/Kentucky)
Advocate Lutheran General Hospital (Chicago, IL)

Other U.S. Facilities with intraoperative MRI.

Boston Children's Hospital, Boston, MA
Miami Children's Hospital, Miami, FL
All Children's Hospital, St. Petersburg FL
Stollery Children's Hospital, Alberta Canada
Cook Children's Hospital, Fort Worth TX
Johns Hopkins Hospital, Baltimore, MD
Children's Healthcare Center, Atlanta GA
Children's National Medical Center, Washington, DC
Children's Hospital, Denver, CO
St. Jude's/Lebonner Children's Hospital, Memphis, TN
Sunrise Hospital Nevada
UCSF
UC Irvine
UCLA
Wilkes-Barre General Hospital, PA
Foothills Hospital, Calgary, Alberta Canada
RWJU Hospital, New Brunswick, NJ
Barrow Neurological Institute, Phoenix, AZ
Massachusetts General Hospital, Boston, MA
OHSU, Portland, Oregon
North Shore University Hospital, NY
Cornell Medical Center, New York, NY

Appendix C

WEB LINKS FOR INTRAOPERATIVE MRI INFORMATION

Odin Medical Technologies - Polestar Low Field Strength Intraoperative MRI
http://www.odinmed.com/site/index.asp

Seaman Family MR Research Center – University of Calgary intraoperative MRI web site – First North American Movable High Field Strength Intraoperative MRI
http://www.med.ucalgary.ca/mrcentre/intraop.html
Case Example from the same center:
http://www.imaginginformatics.ca/facilities/1-5-intera

IMRIS – Moveable ceiling mounted high field strength intraoperative MRI vendor
http://www.med.ucalgary.ca/mrcentre/intraop.html

GE Healthcare – MRI Surgical Suite
http://www.gehealthcare.com/usen/mr/products/mrsurgical_suite.html

Advocate Lutheran General Hospital – Low Field Strength installation with video explanation
http://www.advocatehealth.com/luth/services/advances/mriVideo.html

United Kindom/National Health Service Purchasing and Supply Agency assessment of Polestar N20 Low Field Strength MRI
http://www.pasa.nhs.uk/pasaweb/nhsprocurement/cep/cepnews/archive/evaluationofthemedtronicpolestarimrinavigationsystem.htm

Michigan Department of Community Health Report
Non-Complex (Radio Frequency) Ablations

Ablation:

The Certificate of Need (CON) Commission at their September 19, 2006 Commission meeting announced that they were creating the CC Standards Advisory Committee (CCSAC) in January 2007. They assigned the committee with 5 charges and they also included in the charge that if there were any additional priority issues not in the charge should be reported to the Commission at the December 12, 2006 meeting.

In March 2007, Thoracic Cardiovascular Institute raised the issue of "State of Michigan's regulation prohibiting cardiac electrophysicists from performing catheter-based radiofrequency ablations in hospitals that do not have on-site cardiac surgery programs" with Metro Health of Grand Rapids and sent a copy of the letter to the department. In their opinion, ablations of paroxysmal supraventricular tachycardia, typical atrial flutter, and the AV node have a well established and excellent record and these are procedures with a low risk of serious complications. They included in their letter to Metro Health that the rationale behind the department's rule is very unclear and does not appear to be evidence based. Their argument was while there was clearly data regarding perforations and other complications that may require cardiac surgery, this procedure pertains primarily to "complex" ablation procedures such as atrial ablation (for atrial fibrillation), ablation of ventricular tachycardia and laser lead extraction.

On April 20, 2007, the department sent a response to Metro Health that within the current Certificate of Need review standards for Cardiac Catheterization (CC) services, radiofrequency ablation falls into the therapeutic category. To receive a CON for therapeutic cardiac catheterization services in Michigan, the applicant must provide or have CON approval to provide diagnostic cardiac catheterization. Additionally, the applicant must provide or have CON approval to provide open heart surgery services. They were also referred to CC Standard Advisory Committee which was meeting on April 25th to review the CC review standards.

On April 23, 2007, Metro Health sent a letter to CCSAC Chair along with the letters received from the Thoracic Cardiovascular Institute's doctors who had raised the issue of 'radiofrequency ablations performed in hospitals that do not have on-site cardiac surgery' programs and requested that Metro Health preferred to see amended language that allows for non-complex ablations to be performed at hospitals without open heart surgery. Cases that Metro Health agreed as complex would include atrial fibrillation ablation, and procedures requiring transeptal approach.

While this specific issue was not on the April 25th meeting agenda, the issue was covered under new and emerging technology. In the existing standards, electrophysiology (EP) procedures were classified as diagnostic and therapeutic EP procedures. This committee reviewed the current therapeutic EP procedures and decided to classify them into the following four (4) categories with the appropriate procedure equivalents (weights):

1. Therapeutic EP – Permanent Pacemaker, ICD[1] (adult = 2.5, pediatric=5.0)
2. Therapeutic EP – Ablation Non-AF[2] (adult = 3.0, Pediatric=5.0)
3. Therapeutic EP – Ablation AF or VT[3] (adult = 4.0, Pediatric = 6.0)
4. Therapeutic EP – Cardioversion (Adult = 1.0 and Pediatric = 1.0)

The CCSAC committee members recommended that ablation should remain in therapeutic category and thus must be done at a 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.

The committee did not undertake a discussion to rate "non-complex" versus "complex" in the context of facility ability to perform an 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.

The Department's assessment is that the SAC did, in part, consider the issue during their deliberations. Although the matter may not have been completely resolved to the satisfaction of some, there is no need for further consideration of this issue at this time. This issue could be considered again during the next review cycle in 2011.

[1] Implantable Cardioverter Defibrillator (ICD) – a device that helps control the heart's rhythm, speed and pattern.
[2] AF – Atrial fibrillation
[3] VT – Ventricular Tachycardia – rapid heart arrhythmias

March 10, 2008

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

On April 23rd. 2007 a request was submitted to Carol Joseph, Chairperson of the Cardiac Catheterization Services Standard Advisory Committee (CCSAC) asking that the committee consider reviewing the standard related to ablation procedures. Current standards do not allow hospitals without open heart surgery to perform these procedures in the cardiac catheterization lab.

The standards committee debated if they should review this specific charge or not. Dr. Eric Bates encouraged the committee to review the issue due to its simplicity. In fact, the committee did review a subsection of this particular standard, one that was not requested to be addressed and hence the ablation issue was left with too little time for discussion regarding Metro's original proposal.

Carol Joseph explained that this issue could be addressed soon due to another CCSAC meeting forthcoming within the next year.

On January 24, 2008 the Certificate of Need Commission had a special commission meeting to review standards for 2008. It was at this meeting that Metro and others learned there would not be another CCSAC meeting until 2011.

Metro requested the CON commission consider looking at this issue from the perspective of a work group. On Friday March 7, 2008 Metro was informed the Michigan Department of Health would recommend to the CON commission the issue be considered at the 2011 CCSAC.

While it is no one person or organizations deliberate attempt to delay this request the truth of the matter is the issue will have not be reviewed and truly considered for virtually five years from the original date of request.

To take half a decade to consider amending CON language that is not supported by the American College of Cardiology, The Heart Rhythm Society, University of Michigan, Cleveland Clinic and Thoracic Cardiovascular Institute is inappropriate.

This delay in considering the ablation issue is too extensive. In times when we are seeing technology propel for the better, community based care; the public should not have to wait five years to receive a procedure at a preferred hospital such as Metro Health.

In conclusion, we are asking, the CON commission to please consider looking at this issue of simple ablation prior to the next CCSAC meeting.

Respectfully,

Daniel Witt MHA
Director
Heart & Vascular Center
Metro Health Hospital

Vascular Surgery

The New Medical Technology subcommittee met once since the last CON meeting. The subcommittee needed to evaluate Senator George's request to have vascular surgery regulated as a service under CON.

The committee discussed vascular surgeons. It was decided to make a recommendation to the CON committee not to place vascular surgery under CON regulations.

The reasons:

1. Vascular surgery is an integral part of the practice of medicine and surgery. A modern day hospital should have the capability to perform vascular surgery
2. Some vascular procedures are emergent procedures. A delay by transferring patients could lead to morbidity and mortality.
3. Most hospitals already have vascular surgeons on staff. The disruption to practice patterns would be great.

Therefore, the new medical technology advisory committee recommends that vascular surgery not be placed under CON review.

New Medical Technology

New Medical Technology Advisory Committee (NEWTAC)
Proposed Review Criteria

The NEWTAC is charged, in statute, to assist the Certificate of Need (CON) Commission in reviewing and identifying new medical technology or new medical services that may be appropriate for inclusion into CON regulation as a covered clinical service. The committee should review technology and services giving consideration to any of the following criteria:

1. Review the technology or service in terms of complexity, intensity, and applicability in order to ensure quality, safety, availability, and cost-effectiveness.

2. Review whether the wide spread adoption of the technology or service will significantly contribute to health care cost inflation. The analysis of cost impact should encompass the total costs associated with new technology (including, but not limited to, the costs of dedicated facility and support staff required to operate the new technology).

3. Review the implication of any potential new technology or service on access to quality care, geographically as well as availability under emergent situations.

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.

DRAFT 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		D R	•	•	• —	P		▲						F									
Cardiac Catheterization Services	▮	▮	▮	▮	▮	▮	▮		—	P PH		▲ F	D R •	•	• D R									
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —		P	▲ F									
Hospital Beds	•	•	•	•	•	• R				PH			D R	•	•	•	•	• —	• P PH	•	• ▲ F			
Magnetic Resonance Imaging (MRI) Services	P	•	▲F—		P				▲F				•	•	• R									
Megavoltage Radiation Therapy (MRT) Services/Units**										PH		R	D R	•	• —	• P PH	•	• ▲ F						
Nursing Home and Hospital Long-term Care Unit Beds**	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	•	P •	▲ F •									
Surgical Services										PH			D R	•	• —	• P PH	•	• ▲ F						
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R A	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Commission Approval March 11, 2008

Updated March 7, 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.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	February 25, 2008	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	February 25, 2008	2011
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	February 25, 2008	2009
Surgical Services	June 5, 2006	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	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.