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

Thursday, March 25, 2010

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

APPROVED MINUTES

I. Call To Order

Chairperson Goldman called the meeting to order at 9:39 a.m.

A. Members Present:

Peter Ajluni, DO
James B. Falahee, Jr., JD (left at 1:10 p.m.)
Edward B. Goldman, Chairperson
Marc Keshishian, MD
Gay L. Landstrom
Adam Miller
Michael A. Sandler, MD
Vicky Schroeder
Thomas M. Smith, Vice-Chairperson (left at 12:41 p.m.)
Michael W. Young, DO

B. Members Absent:

Bradley Cory

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Mary Greco
William Hart
Irma Lopez
Kasi Hunziger
Perry Smith
Larry Horvath
Nick Lyon
Tania Rodriquez
Brenda Rogers
Rose Moye

II. Introductions

Chairperson Goldman introduced new commissioners, Gay L. Landstrom and Brian Klott. In addition, he thanked Dottie Deremo and Tom Smith for their service to the Commission.

III. Bylaws

Joe Potchen provided an overview of the Bylaws. (Attachment A)

Motion by Commissioner Falahee, seconded by Vice-Chairperson Smith, to approve the Bylaws as presented. Motion Carried.

Joe Potchen presented an amendment to Article X of the Bylaws. (Attachment B)

Motion by Commissioner Falahee, seconded by Commissioner Ajluni, to accept the amendment to Article X as presented for final action at the June 10th meeting. Motion carried,

IV. Review of Agenda

Motion by Commissioner Falahee, seconded by Vice-Chairperson Smith, to amend and approve the agenda to add Radiation Safety Issue. Motion Carried.

V. Declaration of Conflicts of Interests

None.

VI. Review of Minutes – January 28, 2010

Motion by Commissioner Falahee, seconded by Commissioner Ajluni, to approve the minutes of January 28, 2010 as presented. Motion Carried.

VII. Bone Marrow Transplantation (BMT) Services

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment C)

B. Public Comment:

Dennis McCafferty, Economic of Alliance of Michigan
Matt Jordan, Blue Cross Blue Shield of Michigan (Attachment D)
Joe Uberti, MD, Karmanos
Bob Meeker, Spectrum Health

C. Commission Discussion:

Discussion followed.

D. Commission Final Action:

Motion by Commissioner Falahee, seconded by Commissioner Ajluni, to accept the language as provided (Attachment E) and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Yes – 9, No – 0, Abstained – 1. Motion Carried.

VIII. Heart/Lung and Liver Transplantation Services

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment F)

B. Public Comment:

Dennis McCafferty, Economic Alliance of Michigan
Bob Meeker, Spectrum Health

C. Commission Discussion:

None.

D. Commission Final Action:

Motion by Commissioner Ajluni, seconded by Commissioner Falahee, to accept the language as provided (Attachment G) and move forward to the JLC and Governor for the 45-day review period. Yes – 9, No – 0, Abstained – 1. Motion Carried.

Motion by Commissioner Ajluni, seconded by Commissioner Schroeder, between now and the next meeting, to further review the definition to "initiate" or "implement" related to the length of time to start-up a program and bring back language for proposed action if a change is deemed necessary. Yes – 9, No – 0, Abstained – 1. Motion Carried.

IX. Magnetic Resonance Imaging (MRI) Services

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment H)

B. Public Comment:

Matt Jordan, Blue Cross Blue Shield of Michigan (Attachment D)
Dennis McCafferty, Economic Alliance of Michigan

C. Commission Discussion:

None.

D. Commission Final Action:

Motion by Commissioner Sandler, seconded by Commissioner Falahee, to not move forward the language (Attachment I) to the JLC and Governor for the 45-day review period. Yes – 10, No – 0, Abstained – 0. Motion Carried.

For the record, Chairperson Goldman thanked Dr. Basha for his efforts.

X. Neonatal Intensive Care Services/Beds (NICU)

A. Ms. Rogers gave an overview of the language. (Attachment J)

B. Public Comment:

None.

C. Commission Discussion:

None.

D. Commission Proposed Action:

Motion by Commissioner Falahee, seconded by Commissioner Schroeder to accept the proposed language, forward to JLC, and schedule a Public Hearing. Yes – 9 (Sandler-not in mtg) No – 0, Abstained – 0. Motion Carried.

XI. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

A. Ms. Rogers gave an overview of the process if the Commission chooses to deregulate UESWL Services/Units. A written report was provided to the Commission (Attachment K).

B. Public Comment:

Bob Meeker, Spectrum Health
Monica Harrison, Oakwood (Attachment L)
Sean Gehle, Ascension Health
Melissa Cupp, on behalf of Sparrow Health System (Attachment M)
Jorgen Madsen, United Medical Systems(Attachment N)
Amy Barholtz, Michigan Health & Hospital Association (MHA)
Dennis McCafferty, Economic Alliance of Michigan

C. Commission Discussion:

Discussion followed.

D. Commission Proposed Action:

Motion by Commissioner Ajluni, seconded by Commissioner Falahee, to post the 3/25/10 report (Attachment J) on the web site; further review the NJ deregulation results including other states; consider and review today's testimony; gather information from interested parties; prepare a report; and post the report on the web site prior to the next meeting in June. Yes – 10, No – 0, Abstained – 0. Motion Carried.

XII. Public Comment

Donald Hall, Alliance for Health (Attachment O)

The Commission asked the Department to consider the request during its review of the Nursing Home standards.

Recessed at 11:57 a.m. and reconvened at 12:14 p.m.

XIII. Standing New Medical Technology Advisory Committee (NEWTAC) Report

Commissioner Keshishian gave a brief update of the NEWTAC activity.

XIV. Legislative Report

Mr. Lyon gave a brief update.

XV. Administrative Update

A. Mr. Lyon reported on the Nursing Home discussions.

B. Health Policy Section Update:

Mr. Hart gave a brief administrative update.

Ms. Lopez gave a brief overview on the CT Pilot report (Attachment P).

The Commission had a discussion on radiation safety. After discussion and a review of the CT charge, it was decided that the issue is sufficiently included in the charge.

C. CON Evaluation Section Update:

Mr. Horvath gave an update on the CON Evaluation Section which included an update on changes to the draft administrative rules. (Attachments Q and R)

D. Ms. Greco provided an overview of the administrative rules process.

E. Mr. Potchen gave an overview of the Commission's role in the administrative rules process.

Motion by Commissioner Falahee, seconded by Commissioner Sandler, that the Commission approve the proposed procedural administrative rules for the CON program submitted by the Department and approve the Department proceeding with the promulgation of administrative rules for the CON program. Yes – 9, No – 0, Abstained – 0. Motion Carried.

XVI. Legal Activity Report

Mr. Potchen gave an overview of the Legal Activity Report. (Attachment S)

XVII. Future Meeting Dates

June 10, 2010
September 23, 2010
December 15, 2010

XVIII. Public Comment

Cheryl Miller, Health Network Trinity Health (Attachment T)

XIX. Review of Commission Work Plan

Ms. Rogers gave an overview of the Work Plan (Attachment U). Discussion followed.

Motion by Commissioner Ajluni, seconded by Commissioner Sandler, to approve the Work Plan as presented. Yes – 8, No – 0, Abstained – 0. Motion Carried.

XX. Election of Officers

Motion by Commissioner Young, seconded by Commissioner Sandler to nominate and elect Commissioner Ajluni as Vice-Chairperson for the Commission.

Motion by Commissioner Miller, seconded by commissioner Schroeder, to nominate and elect Commissioner Falahee as Vice-Chairperson for the commissioner.

Commissioner Ajluni withdrew his nomination.

A vote on the motion to nominate and elect Commissioner Falahee as Vice-Chairperson occurred. Yes – 7, No – 0, Abstained – 1. Motion Carried.

Chair Goldman mentioned that Commissioner Ajluni will also be included in Executive Committee activities.

XXI. Adjournment

Motion by Commissioner Sandler, seconded by Commissioner Miller, to adjourn the meeting at 1:31 p.m. Motion Carried.

CERTIFICATE OF NEED (CON) COMMISSION BYLAWS

ARTICLE I - PREAMBLE

ARTICLE II - DEFINITIONS

ARTICLE III - GENERAL PURPOSE

ARTICLE IV - ~~STANDARD ADVISORY COMMITTEES~~MEMBERSHIP OF THE COMMISSION

ARTICLE V - ~~MEMBERSHIP~~ MEETINGS OF THE ~~CON~~ COMMISSION

ARTICLE VI - ~~MEETINGS OF THE CON COMMISSION~~OFFICERS AND PROCEDURES FOR ELECTING OFFICERS

ARTICLE VII - ~~OFFICERS AND PROCEDURES FOR ELECTING OFFICERS~~COMMITTEES

ARTICLE VIII - ~~PARLIAMENTARY~~ PROCEDURE AND LEGAL COUNSEL

ARTICLE IX - STANDARDS OF CONDUCT BY ~~CON~~ COMMISSION MEMBERS AND CONFLICT OF INTEREST PROVISIONS

ARTICLE X - AMENDMENTS OF BYLAWS

Amended 03/08/05
Amended 09/26/94
Amended 09/14/92
Approved 08/01/89

ARTICLE ~~1~~ I - PREAMBLE

The Michigan ~~Certificate of Need~~CON Commission (~~CON~~ Commission) is created in the Michigan Department of Community Health (the ~~department~~Department) and is established ~~pursuant to~~under the Michigan Public Health Code, 1978 P~~.~~A~~.~~ 368, MCL 333.1101, et seq., ~~MSA 14.15 (1101) et seq.,~~ as amended ~~by Public Acts 308, 331 and 332 of 1988, and 396 of 1993, which augmented the Public Health Code by the addition of Part 222~~ (the Code) ~~and amended by Public Act 619 of 2002~~. The Bylaws developed by the ~~CON~~ Commission ~~shall~~ remain in effect until ~~otherwise~~ amended as provided for in Article X.

ARTICLE II - DEFINITIONS

Unless defined in these Bylaws, ~~The~~ the terms used in these ~~bylaws~~ Bylaws have the meaning ascribed to them in Parts 201 and 222 of the Code.

ARTICLE III - GENERAL PURPOSE

The duties of the Commission are set forth in Section 22215 of the Code. The ~~CON~~ Commission ~~shall~~ exercises its duties to promote all of the following:

A. The availability and accessibility of quality health services at reasonable cost and with reasonable geographic proximity for all people in the state;

B. Appropriate differential consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents; and

C. Consideration of the impact of a proposed restriction on the acquisition of or availability of covered clinical services on the quality, accessibility, and cost of health services in this state.

~~ARTICLE IV - STANDARD ADVISORY COMMITTEES~~

~~If the Commission determines it necessary, it may appoint standard advisory committees to assist in the development of proposed CON review standards in accordance with section 333.22215(1)(l).~~

~~A. The duties of a standard advisory committee shall be developed by the Commission at a regular or special meeting. A standard advisory committee's duties shall be adopted by a majority of the Commission.~~

~~B. The duties of a standard advisory committee shall be set forth in a written charge enumerating the duties delegated to it by the Commission.~~

~~C. The language of the written charge may be adopted by vote of the commission or the Commission may delegate the Chairperson to write the charge, consistent with the action of the Commission.~~

~~D. The members of a standard advisory committee shall be appointed by the chairperson consistent with statutory requirements and the recommendations of the Commission.~~

~~E. The appointment of a standard advisory committee shall be effective as of the date of the first meeting of the committee.~~

~~F. The chairperson of a standard advisory committee shall be appointed by the chairperson of the Commission.~~

~~G. A member of a standard advisory committee shall be subject to the provisions against conflicts of interest consistent with Article IX of these bylaws.~~

~~H. All meetings of standard advisory committees shall comply with the provisions of the Michigan Open Meeting Act, being Public Act 267 of 1976, as amended.~~

ARTICLE IV - MEMBERSHIP OF THE ~~CON~~ COMMISSION

A. Size and Composition

The ~~CON~~ Commission ~~shall~~ consists of 11 members ~~appointed by the Governor with the advice and consent of the Senate pursuant to~~as designated under Section 22211 of the Code.

~~1. Two individuals representing hospitals.~~

~~2. One individual representing physicians licensed under part 175 to engage in the practice of medicine.~~

~~3. One individual representing physicians licensed under part 175 to engage in the practice of osteopathic medicine and surgery.~~

~~4. One individual who is a physician licensed under part 170 or 175 representing a school of medicine or osteopathic medicine.~~

~~5. One individual representing nursing homes.~~

~~6. One individual representing nurses.~~

~~7. One individual representing a company that is self-insured for health coverage.~~

8. One individual representing a company that is not self-insured for health coverage.

9. One individual representing a nonprofit health care corporation operating pursuant to the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1703.

10. One individual representing organized labor unions in this state.

B. Term of Office

Commission members will serve a term as set forth in Section 22211(3) of the Code.

1. Newly appointed Commissioners take office upon appointment of the Governor. Unless rejected by the Senate, Commissioners then serve until their term of office expires and their successor takes office or their resignation is accepted by the Governor.

2. The members of the CON Commission, with the exception of initial members, shall serve for a term of three years or until a successor is appointed.

C. Quorum, Voting Procedures, and Proxy Votes

1. A majority of the CON Commission members appointed and serving shall constitute a quorum. Final action by the CON Commission shall be only by affirmative vote of a majority of CON Commission members appointed and serving.

2. Actions not resulting in final action (including recommending action by the full commission or completing other planning tasks) may be made by a majority of those in attendance.

3. A CON Commission member shall not vote by proxy. A proxy of a CON Commission member shall not be seated, nor shall they vote, offer motions or second motions.

ARTICLE V~~I~~ - MEETINGS OF THE ~~CON~~ COMMISSION

A. Quorum, Voting Procedures, and Proxy Votes

1. Section 22213 of the Code defines a quorum for the Commission. With an 11 member Commission, a quorum is 6 of the 11 members appointed and serving.

2. Final action by the Commission shall be only by affirmative vote of a majority of the Commission members appointed and serving. Any action taken in the absence of a quorum is invalid. If the Commission properly notices a meeting under the Open Meetings Act, but lacks a quorum when it actually convenes, the Commission members in attendance may receive reports and comments from the public or from the Department, ask questions, and comment on matters of interest.

3. Commission members cannot assign a proxy.

B. Compliance ~~With~~with Open Meetings Act

The ~~CON~~ Commission ~~shall~~ must adhere to the provisions of the Michigan Open Meetings Act, ~~being Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261, et seq.

~~B~~C. Governance under Robert's Rules of Order Revised

The Commission's procedural activities ~~shall be~~are governed by Robert's Rules of Order Newly Revised if~~, in so far as~~ they are consistent with state law and these ~~bylaws~~Bylaws.

~~C. Notice of Meetings~~

~~The Department shall make available the times and places of the meetings of the CON Commission. The Department shall also keep minutes of such meetings and a record of the actions of the CON Commission.~~

D. Regular and Special Meetings

1. In September, ~~The~~ the ~~CON~~ Commission ~~shall hold regular meetings quarterly at places and on dates fixed by the CON Commission~~must announce~~d in September, preceding each calendar year~~ the regular meeting dates for the following year. Special meetings may be called as provided for in Section 22213 of the Code.

2. ~~Special meetings may be called by the chairperson of the CON Commission, by not less than three CON Commission members, or by the Department.~~

~~3.~~ A regular or special meeting of the ~~CON~~ Commission may be recessed and reconvened consistent with the provisions of the Michigan Open Meetings Act, ~~being Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261, et seq.

E. Meeting Attendance

1. ~~Members of the CON~~ Commission members are expected to attend all regular and special meetings except on those occasions where good cause exists.

2. When a Commission member ~~of the CON Commission is aware that he or she~~ will be unable to attend a regular or special meeting, every effort should be made to give advance notice to the Department, which ~~shall~~ must notify the Commission chairperson or vice-chairperson ~~of the CON Commission~~.

3. The Commission chairperson ~~of the CON Commission shall~~ determines whether ~~a~~ good cause exists for the absence of a member from a regular or special meeting of the ~~CON~~ Commission. When the attendance of the chairperson is under question, the responsibility for determining good cause falls to the Commission vice-chairperson ~~of the CON Commission~~.

4. Pursuant to the Code, ~~The~~ the Governor may remove a ~~CON~~ Commission member from office for failure to attend 3 consecutive meetings in a 1-year period. The Commission chairperson ~~or vice-chairperson of the CON Commission shall~~ must promptly inform the Governor's office (a) if a member fails to attend the statutory minimum number of consecutive meetings in a 1-year period, and (b) ~~of such situations, and shall~~ indicate ~~as to~~ whether good cause existed for such absences.

F. Teleconferencing

Commission members may participate in meetings by ~~Teleconferencing~~ teleconferencing ~~shall be allowed in accordance~~consistent with the Open Meetings Act (~~Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261. et seq). Upon approval of the Chairperson, ~~CON~~ Commission members may appear at a meeting via electronic device, including speaker phone or interactive television, provided that a quorum is present at the meeting site and all individuals attending the meeting can hear, and can be heard by, the Commissioner(s) attending via electronic device. Commission members participating in meetings by teleconference cannot use teleconferencing to vote but may speak on matters being considered.

G. Agenda and Background Materials

1. In consultation with the Department and other Commission members, the ~~Chairperson~~ chairperson ~~shall~~ must ~~determine~~ set a tentative agenda for each meeting.

2. No later than 7 days before each meeting, the Department must place the tentative agenda ~~shall be placed~~ on the appropriate section of the Department's Web site. ~~No later than 5 days prior to each meeting the text of any proposed or final actions and relevant background materials shall be delivered to each Commissioner (using overnight delivery or Email, as necessary) and shall be posted on the appropriate section of the Department's Web site.~~

3. No later than 5 days before each meeting, the Department must deliver the text for any CON review standards for proposed or final actions and relevant background to each Commissioner (using overnight delivery or Email, as necessary) and post it on the appropriate section of the Department's Web site. ~~Urgent~~ At the start of a meeting, the Commission, by unanimous approval, may add ~~action items~~CON review standards, that meet statutory requirements~~,~~ for proposed or final action, to the agenda~~, meeting the statutory requirements, may be added to the agenda, on the unanimous approval by the Commission at the start of a meeting~~.

ARTICLE VI~~I~~ - OFFICERS AND PROCEDURES FOR ELECTING OFFICERS

A. Election of Chairperson and Vice-Chairperson

~~At its first meeting and~~ On an annual~~ly~~ basis ~~thereafter~~, the ~~CON~~ Commission ~~shall~~ must elect a chairperson and vice-chairperson for a 1-year term not to exceed ~~three~~ 3 consecutive terms. The chairperson and vice-chairperson ~~shall~~ cannot be members of ~~separate~~ the same major political ~~parties~~party.

B. Procedures for Selecting Officers

1. ~~Nominations for officers may be made by a~~Any ~~CON~~ Commission member may nominate officers if the member is appointed and serving and ~~in attendance~~ attending ~~at~~ the meeting where the selection of officers is to occur.

2. ~~Election of o~~Officers ~~shall be determined by an affirmative vote of~~are elected by a majority vote by the ~~of CON~~ Commission members appointed and serving.

C. Responsibilities of Officers

1. The chairperson presides over Commission meetings. In ~~The~~ the chairperson's ~~or, in his or her~~ absence, the vice-chairperson ~~shall~~ presides over ~~the CON~~ Commission ~~at all its regular and special~~ meetings. ~~In the event that~~ If neither the chairperson nor vice-chairperson is able to preside

over any portion of a meeting ~~or a portion thereof~~, the remaining members of the ~~CON~~ Commission ~~shall~~ must select a temporary presiding officer.

2. In the chairperson's absence, the vice-chairperson or the temporary presiding officer will perform ~~The~~ the duties designated to the chairperson in the ~~Public Health~~ Code and these ~~bylaws~~Bylaws~~, in the absence of the chairperson shall be performed by the vice-chairperson or the temporary presiding officer~~.

D. Filling Vacancies in Officers

1. If the office of chairperson becomes vacant for any reason, the vice-chairperson ~~shall~~ must vacate the~~ir~~ vice-chairperson position and ~~become~~ serve as the chairperson ~~of the CON Commission, serving~~for the remaining months of the chairperson's ~~one~~1-year term.

2. If the office of vice-chairperson becomes vacant for any reason, the ~~CON~~ Commission ~~shall~~ must elect a new vice-chairperson by an affirmative vote of a majority of those members appointed and serving, and that person ~~shall~~ will serve the remaining months of the vice-chairperson's term.

3. If the offices of chairperson and vice- chairperson become vacant simultaneously, the ~~CON~~ Commission ~~shall~~ must conduct a special election to fill those positions. New officers ~~shall~~ must be elected by an affirmative vote of a majority of those members appointed and serving and they ~~shall~~ must serve the remaining months of the chairperson's and vice-chairperson's term.

ARTICLE VII – COMMITTEES

A. Standing New Medical Technology Advisory Committee (NEWTAC)

Composition and duties of the NEWTAC are set forth in Section 22241 of the Code.

B. Standard Advisory Committee (SAC)

If the Commission determines it necessary, it may appoint a SAC to assist in the development of proposed CON review standards in accordance with Section 333.22215(1)(l).

1. The Commission must adopt the duties for a SAC. The duties of the SAC must be defined in a written charge. The written charge to the SAC may be adopted by vote of the Commission, or the Commission may instruct the

chairperson to write the charge, consistent with the language adopted by the Commission.

2. The term of any SAC expires 6 months from the first meeting of the SAC or at an earlier date as specified by the Commission.

3. The chairperson appoints the members of a SAC consistent with statutory requirements and the criteria outlined in this subpart.

   a. The Department determines whether a candidate for a SAC meets the following criteria:

      i. The candidate has not served on more than 2 SACs within any 2-year period.

      ii. The candidate is not a lobbyist registered under 1978 PA 472, MCL 4.411 TO 4.431.

      iii. The candidate is not affiliated with a program with a Letter of Intent (LOI) or a pending application in the CON process related to the standard(s) being reviewed.

   b. A SAC consists of a 2/3 majority of experts with professional competence in the subject matter of the proposed standard. The Department determines whether a candidate seeking to be appointed as an expert to a SAC meets the following criteria:

      i. The candidate is a clinician, e.g., doctor, nurse, or other health care professional, who has specific education, training, and experience in the service being considered; or the candidate is a representative of an organization concerned with licensed health facilities, e.g., administrator or a specialist in the subject matter of the standard being reviewed, who have specific education, training, and experience in the service being considered.

      ii. Professional competence demonstrated by relevant professional activity over a majority of the last five years.

   c. A SAC includes representatives of health care provider organizations concerned with licensed health facilities or licensed health professions, as well as representatives of organizations concerned with health care consumers, and the purchasers and payers of health care services.

   d. Only one employee, director, or officer of any one health system, either directly or through the subsidiaries of a system can be appointed as a

member of the same SAC. For purposes of these Bylaws, "health system" means facilities where health care is provided and includes without limitation hospitals, nursing homes, county medical care facilities, home health agencies, hospices, out-patient surgical facilities, laboratories, rural health clinics, freestanding surgical units, ambulatory surgical units, and end stage renal disease and dialysis facilities.

4. The Commission chairperson appoints the chairperson of a SAC.

C. Members of the NEWTAC and a SAC are subject to the following provisions:

1. Conflicts of interest consistent with Article IX of these Bylaws.

2. Teleconferencing consistent with Article V(F) of these Bylaws.

3. Michigan Open Meetings Act, 1976 PA 267, as amended, MCL 15.261, et seq.

ARTICLE VIII - ~~PARLIAMENTARY~~ PROCEDURE AND LEGAL COUNSEL

A. ~~The Attorney General of the State of Michigan, or his or her duly designated Assistant Attorney General, shall serve as parliamentarian for the CON Commission. The duties of the parliamentarian shall be to advise the presiding officer with respect to any matters pertaining to parliamentary procedure.~~

~~B. Any~~The presiding officer will use the laws of the State, these Bylaws, and Robert's Rules of Order Newly Revised to resolve any question arising concerning procedure at a meeting of the ~~CON~~ Commission ~~shall be resolved by the presiding officer in accordance with the laws of the State, these bylaws, and Robert's Rules of Order Revised~~.

~~C~~B. The Attorney General of the State of Michigan, or ~~his or her~~the duly designated Assistant Attorney General, ~~shall~~ serves as legal counsel to the ~~CON~~ Commission.

ARTICLE IX - STANDARDS OF CONDUCT BY ~~CON~~ COMMISSION MEMBERS AND CONFLICT OF INTEREST PROVISIONS

A. ~~CON~~ Commission members are subject to the provisions of:

1. 1968 PA 317, MCL 15.321 to 15.330 (contracts of public servants with public entities);

2. 1973 PA 196, MCL 15.341 to 15.348 (code of ethics for public officers and employees); and

3. 1978 PA 472, MCL 4.411 to 4.431, (lobbyists and lobbying regulation~~);~~).

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for ~~CON~~ Commission members ~~shall~~ exists when the individual member has a financial or personal interest in a matter under consideration by the ~~CON~~ Commission. The personal interest of a ~~CON~~ Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.

2. ~~CON~~ A Commission member~~s shall~~ does not ~~be in violation~~ violate ~~of~~ the State Ethics Act~~, supra,~~ if the member abstains from deliberating and voting upon ~~review standards~~the matter in which the member's personal interest is involved.

3. ~~CON~~ A Commission member~~s~~ may deliberate and vote on ~~standards~~ matters of general applicability~~; that is, those standards~~ that do not exclusively benefit certain health care facilities or providers who employ the ~~CON~~ Commission member, even if the ~~standard of general applicability would benefit~~matter involves the member's employer or those for whom the member's employer does work.

4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A ~~CON~~ Commission member ~~shall~~ must disclose ~~that he or she~~any ~~has a~~ potential conflict of interest~~,~~ after the start of a meeting, ~~at the commencement of~~ when the Commission begins to consider~~ation of~~ a substantive matter ~~before the CON Commission~~, or, where consideration has already commenced, when~~, at the point where~~ a conflict or potential conflict of interest becomes apparent to the member.

2. After a meeting is called to order and the agenda reviewed, the chairperson ~~shall~~ must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.

3. ~~Prior to a vote on a substantive matter before the CON Commission, the presiding officer shall inquire of the membership as to the existence of a conflict of interest.~~

~~4. A conflict of interest shall not affect the existence of a quorum for purposes of a vote~~ A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.

~~5~~4. Where a Commission member has not discerned ~~that she/he may have~~ any conflict of interest ~~and must voluntarily abstain from discussion and vote~~, any other Commission member may raise a concern ~~as to~~ whether another member has a conflict of interest on a ~~substantive~~ matter. If a second member joins in the concern, ~~there shall be~~the Commission must discuss~~ion~~ and ~~a~~ vote on whether the member has a conflict of interest ~~prior to~~before continuing discussion or taking any action on the ~~substantive~~ matter under consideration. The question of conflict of interest ~~shall be~~is settled by an affirmative vote of a majority of those ~~CON~~ Commission members appointed and serving, excluding the member or members in question.

~~6~~5. The minutes of the meeting ~~shall~~ must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

ARTICLE X - AMENDMENTS OF BYLAWS

A. Any amendments to these ~~bylaws~~Bylaws ~~shall~~ must be proposed by the ~~CON~~ Commission or presented in writing to the ~~CON~~ Commission by the Department at least 30 days in advance of the meeting where final action is scheduled to be taken.

B. ~~Any amendments to these bylaws shall be deemed to be approved upon an affirmative vote of a majority of the CON Commission members appointed and serving.~~ Amendments to the ~~bylaws~~Bylaws ~~shall~~ become effective upon approval or on ~~such~~ a later date ~~as is~~if specified within the amendments.

ARTICLE X - AMENDMENT OF BYLAWS

A. At a regular or special meeting, a majority of Commission members appointed and serving may propose an amendment to these Bylaws. Any proposal by the Commission to amend these Bylaws must be made at least 30 days in advance of the meeting where final action regarding the amendment is taken.

B. Any Commission member may propose an amendment to these Bylaws. Any proposal by a Commission member to amend these Bylaws must be presented to the Commission and the Department, in writing, at least 30 days in advance of the meeting where final action regarding the amendment is taken.

C. The Department may propose an amendment to these Bylaws. Any proposal by the Department to amend these Bylaws must be presented to the Commission, in writing, at least 30 days in advance of the meeting where final action regarding the amendment is taken.

D. Any amendment to these Bylaws Bylawsbecomes effective on the date the Commission takes final action to approve the amendment or on a later date if specified in the amendment.

E. Upon adoption of any amendment to these Bylaws, the Department must provide the Commission members with a copy of the updated Bylaws.

F. These Bylaws supercede and replace the Bylaws approved and amended by the Commission on March 25, 2010. *(NOTE: This subsection would replace listing all of the amendment dates in the footer.)*

Michigan Department of Community Health (MDCH or Department)
MEMORANDUM
Lansing, MI

Date: March 17, 2010

TO: Irma Lopez

FROM: Kasi Hunziger

RE: Summary of Public Hearing Comments on Bone Marrow Transplantation Standards and MDCH Policy Staff Analysis

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the Bone Marrow Transplant (BMT) Standards at its December 9, 2009 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed BMT Services Standards on February 10, 2010. 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 five organizations and is summarized as follows:

1. *Dennis McCafferty, The Economic Alliance of Michigan:*
   The Economic Alliance of Michigan (EAM) does not support increasing the number of BMT programs in Michigan. They believe that the standards should maintain a cap of three programs in Michigan as the three current programs are meeting the access and quality needs of the community.

   EAM supports the increase in the annual volume requirement for new programs. Additionally, they support the proposed language of requiring that all new adult programs provide a minimum of 10 allogeneic transplants annually. They believe this will ensure that the level of quality being provided by any new program is of the highest standards.

   The Economic Alliance of Michigan supports the elimination of provisions within the standards that reference autologous only transplant programs.

   Lastly, the Economic Alliance of Michigan would like to see that the Department actively recruit individuals during application periods for SACs when they see that there is a lack of appropriate candidates. For the BMT SAC there was no representation from northern Michigan as nobody expressed an interest from that geographic representation. By the

Department recruiting, it would assure that there is geographic representation as well as representation of different perspectives.

2. *Robert Meeker, Spectrum Health:*
   Spectrum Health strongly supports the proposed standards with regard to the creation of the second planning area for adult BMT programs. Also, Spectrum supports the increased volume requirement for new programs and, the requirement that new programs must perform a minimum of 10 allogeneic transplants annually. Lastly, Spectrum Health supports the revised comparative review criteria within the standards.

3. *Carol Christner, Barbara Ann Karmanos Cancer Institute:*
   Karmanos supports the SAC recommendation to continue regulation of BMT services. Additionally, they support the recommendation by the SAC to create a second planning area that mirrors the pediatric BMT planning area to allow for one new program in that area. Lastly, they agree with the SAC that no further expansion of BMT programs is needed within Southeast Michigan.

4. *Patrick O'Donovan, Beaumont Hospitals:*
   Beaumont Hospital opposes the proposed standards. They state a concern is that there has never been a methodology behind the BMT standards and, during the SAC process, one was still not established. They believe that this goes against a basic tenet of CON that the standards be based on an objective, need-based methodology.

   Beaumont requests that the Commission consider either removing BMT from CON regulations or to quickly consider an institution specific methodology for BMT services.

5. *Barbara Jackson, Blue Cross Blue Shield Michigan (BCBSM/BCN):*
   BCBSM/BCN remains unconvinced that there is a need for an additional BMT program in Michigan. Dr. Ruane who represented BCBSM by sitting on the SAC states that he is not convinced that any improved access that may occur would outweigh the problems caused by a decreased volume in the existing centers.

Staff Analysis and Recommendations

The Department maintains that BMT services continue to need ongoing monitoring of the quickly changing issues of access, stem cell research implications, impact of cancer treatments, and whether there should be an appropriate needs based methodology developed. There are vastly different and polarized points of view regarding the actual language of the standards that have been voiced; particularly over the past few years as the technology is changing. The focus has been on drafting language to address immediate requests.

This polarization impedes the ability of the state to have a thorough debate of the broader implications of the changing field, and addressing BMT in a comprehensive manner and within the context of current medical technologies.

The Department further continues to oppose the splitting of the state into two planning areas for adult programs. The highly specialized nature of this service supports that the planning area be the entire state rather than two regions.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION (BMT) 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 bone marrow transplantation services.~~ THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, BONE MARROW TRANSPLANTATION IS A COVERED CLINICAL SERVICE. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION ~~2~~22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

(2) ~~A bone marrow transplantation service is a covered clinical service for purposes of Part 222 of the Code.~~

~~(3)~~ A ~~bone marrow transplantation~~ BMT service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic ~~bone marrow transplant~~ BMT procedures.

~~(4)~~ (3) An existing ~~bone marrow transplantation~~ BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing ~~bone marrow transplantation~~BMT service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

~~(5) The Department shall use Sections 3, 7 & 8, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

~~(6) The Department shall use Sections 4, 5 & 6, 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) As used in these standards:

(a) "Acquisition of a ~~bone marrow transplantation~~ BMT service" means the acquisition (including purchase, lease, donation, or other arrangement) of an existing ~~bone marrow transplantation~~ BMT service.

(b) "Adult~~,~~" ~~for purposes of these standards,~~ means an individual age 18 or older.

(c) "Allogeneic" means transplantation between genetically nonidentical individuals of the same species.

(d) "Autologous" means transplantation in which the donor and recipient are the same individual.

(e) "Bone marrow transplantation service" OR "BMT SERVICE" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.

(f) "Cancer hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section 1886 (d)(1)(B)(v) of the Social Security Act, as amended.

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

(h) "Comparative group" means the applications that have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

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

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

(k) "Department inventory of ~~bone marrow transplantation~~ BMT services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) operating ~~bone marrow transplantation~~ BMT services for which the operation of that service did not require a CON; and (iii) ~~bone marrow transplantation~~ BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the ~~bone marrow transplantation~~ BMT service is authorized.

(l) "Existing ~~bone marrow transplantation~~ BMT service," for purposes of Section 3(5) of these standards, means any of the following: (i) a ~~bone marrow transplantation~~BMT service listed on the Department inventory, (ii) a proposed ~~bone marrow transplantation~~BMT service under appeal from a final decision of the Department, or (iii) a proposed ~~bone marrow transplantation~~BMT service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(m) "Health service area" or "HSA" means the geographic area set forth in Section 9.

~~(n) "Implementation plan" means a plan that documents how a proposed bone marrow transplantation service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:~~

~~(i) each component or activity necessary to begin performing the proposed bone marrow transplantation service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;~~

~~(ii) the time table for completing each component or activity specified in subsection (i); and~~

~~(iii) if the applicant previously has been approved for a bone marrow transplantation service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.~~

(~~o~~N) "Initiate" or "implement" ~~for purposes of these standards,~~ means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2)~~, if authorized by the Department.~~

(~~p~~O) "Initiate a ~~bone marrow transplantation~~BMT service" means to begin operation of a ~~bone marrow transplantation~~BMT service at a site that does not provide either adult or pediatric ~~bone marrow transplantation~~BMT services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric ~~bone marrow transplantation~~BMT service, and a pediatric service that is proposing to provide an adult ~~bone marrow transplantation~~BMT service. The term does not include beginning operation of a ~~bone transplantation~~ BMT service by a cancer hospital which acquires an existing ~~bone marrow transplantation~~BMT service provided that all of the staff, services, and programs required under section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the ~~bone marrow transplantation~~BMT service is being acquired.

(~~q~~P) "Institutional Review Board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(~~r~~Q) "Licensed site" means ~~either:~~

~~(i) in the case of a single site hospital,~~ the location of the ~~facility~~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 unit of the health facility as authorized by license and listed on that licensee's certificate of licensure~~.

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

(~~t~~S) "Pediatric" means~~, for purposes of these standards,~~ any patient 20 years of age or less or any patient with congenital conditions or diseases for which ~~bone marrow transplantation~~BMT is a treatment.

(~~u~~T) "Planning area" means:

~~(i) for an adult bone marrow transplantationBMT service, the state of Michigan.~~

~~(ii) for a pediatric bone marrow transplantationBMT service, either:~~

(~~A~~I) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(~~B~~II) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

(~~v~~U) "Qualifying project" means each application in a comparative group that 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.

(~~w~~V) "Survival rate" means~~, for purposes of these standards,~~ the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(W) "TUMOR REGISTRY" 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.

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

Section 3. Requirements ~~for approval for applicants proposing~~ to initiate a ~~bone marrow transplantation~~BMT service

Sec. 3. ~~(1)~~ An applicant proposing to initiate a ~~bone marrow transplantation~~ BMT service shall demonstrate the following requirements:

(1) An applicant shall specify in the application whether the proposed service will perform either or both adult and pediatric ~~bone marrow transplant~~ BMT procedures.

(2) An applicant shall specify the licensed ~~hospital~~ site at which the ~~bone marrow transplantation~~ BMT service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric ~~bone marrow transplantation~~ BMT service shall demonstrate that the licensed ~~hospital~~ site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.

(xii) pulmonary medicine.

(xiii) radiation oncology.

(xiv) radiology.

(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric ~~bone marrow transplant~~ BMT procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.

(ii) immunology.

(iii) neurosurgery.

(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed ~~bone marrow transplantation~~BMT service. "IMPLEMENTATION PLAN" MEANS A PLAN THAT DOCUMENTS HOW A PROPOSED BMT SERVICE WILL BE INITIATED WITHIN THE TIME PERIOD SPECIFIED IN THESE

STANDARDS OR THE CON RULES. AT A MINIMUM, THE IMPLEMENTATION PLAN SHALL IDENTIFY:

(A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE PROPOSED BMT SERVICE INCLUDING, BUT NOT LIMITED TO, THE DEVELOPMENT OF PHYSICAL PLANT REQUIREMENTS, SUCH AS AN INTENSIVE CARE UNIT CAPABLE OF TREATING IMMUNO-SUPPRESSED PATIENTS, EQUIPMENT ACQUISITIONS, AND RECRUITMENT AND EMPLOYMENT OF ALL PHYSICIAN AND SUPPORT STAFF;

(B) THE TIME TABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN SUBSECTION (~~I~~A); AND

(C) IF THE APPLICANT PREVIOUSLY HAS BEEN APPROVED FOR A BMT SERVICE FOR WHICH EITHER THE CON EXPIRED OR THE SERVICE DID NOT PERFORM A TRANSPLANT PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT CHANGES HAVE OR WILL BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE INITIATED AND PROVIDED ON A REGULAR BASIS.

(5)(a) An applicant shall demonstrate that the number of existing adult ~~bone marrow transplantation~~ BMT services DOES NOT EXCEED THREE (3) ADULT BMT SERVICES IN PLANNING AREA ONE IDENTIFIED IN ~~in the planning area identified in~~ Section 2(1)(~~u~~T)(i) OR ONE (1) ADULT BMT SERVICE IN PLANNING AREA TWO IDENTIFIED IN SECTION 2(1)(T)(II) AND THAT APPROVAL OF THE PROPOSED APPLICATION WILL NOT RESULT IN THE TOTAL NUMBER OF ADULT BMT SERVICES EXCEEDING THE NEED FOR EACH SPECIFIC PLANNING AREA.~~does not exceed three (3) adult bone marrow transplantation BMT services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation BMT services exceeding three (3) in the planning area.~~

(b) An applicant shall demonstrate that the number of existing pediatric ~~bone marrow transplantation~~BMT services does not exceed two (2) pediatric ~~bone marrow transplantation~~BMT services in planning area one identified in Section 2(1)(~~u~~T)~~(ii)(A~~) or one (1) pediatric ~~bone marrow transplantation~~BMT service in planning area two identified in Section 2(1)(~~u~~T)(ii)~~(B)~~ and that approval of the proposed application will not result in the total number of pediatric ~~bone marrow transplantation~~BMT services exceeding the need for each specific ~~pediatric~~ planning area.

(6)(a) An applicant proposing to initiate an adult ~~bone marrow transplantation~~BMT service ~~that will perform only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall project that at least ~~10~~30 TRANSPLANTS, OF WHICH AT LEAST 10 ARE allogeneic transplant procedures, will be performed in the third 12-months of operation. ~~An applicant proposing to initiate an adult bone marrow transplantationBMT service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.~~

(b) An applicant proposing to initiate a pediatric ~~bone marrow transplantation~~BMT service ~~that will perform only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall project that at least 10 TRANSPLANTS, OF WHICH 5 ARE allogeneic transplant procedures, will be performed in the third 12-months of operation. ~~An applicant proposing to initiate a pediatric bone marrow transplantationBMT service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.~~

(c) An applicant proposing to initiate both an adult and a pediatric ~~bone marrow transplantation~~BMT service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed ~~hospital~~ site at which the proposed ~~bone marrow transplantation~~BMT service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric ~~bone marrow transplantation~~BMT service shall demonstrate that the licensed ~~hospital~~ site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in ~~bone marrow transplantation~~BMT or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric ~~bone marrow transplantation~~BMT service shall submit, in its application, a written consulting agreement with an existing ~~bone marrow transplantation~~BMT service~~, that meets each of the requirements in subsection (b)~~. THE WRITTEN CONSULTING AGREEMENT MUST BE WITH AN EXISTING IN-STATE OR OUT-OF-STATE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITED TRANSPLANT UNIT THAT PERFORMS BOTH ALLOGENIC AND AUTOLOGOUS TRANSPLANTS FOR EITHER ADULT AND/OR PEDIATRICS. THE TERMS OF THE AGREEMENT AND THE ROLES AND RESPONSIBLITIES OF BOTH THE EXISTING AND PROPOSED SERVICE~~,~~ SHALL INCLUDE AT LEAST THE FOLLOWING:

~~(b) The written consulting agreement required by subsection (a) shall specify the term of the agreement and the roles and responsibilities of both the existing and proposed service, including at least the following:~~

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform ~~bone marrow transplant~~BMT procedures.

(ii) One or more representatives of the existing ~~bone marrow transplantation~~BMT service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

(iv) Specify a schedule of site visits by staff of the existing ~~bone marrow transplantation~~BMT service that, at a minimum, includes:

(A) ~~6~~3 visits during the first 12-months of operation of the proposed service.

(B) ~~4~~3 visits during each the second 12-months and third 12-months of operation of the proposed service.

(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:

(A) a review of the number of patients transplanted.

(B) transplant outcomes.

(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.

(D) all deaths occurring within 100 days from transplant.

(E) each of the requirements of subdivision (iii).

(vi) Specify that a written report and minutes of each site visit shall be completed by the existing ~~bone marrow transplantation~~BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).

(vii) Specify that the existing ~~bone marrow transplantation~~BMT service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.

(viii) Specify that the existing ~~bone marrow transplantation~~BMT service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.

(B~~c~~) For purposes of subsection (10), "existing ~~bone marrow transplantation~~BMT service" means a service that meets all of the following:

(i) currently is performing and is ~~Foundation for Accreditation of Cell Therapy (~~FACT~~)~~ accredited in, the types of transplants (allogeneic AND~~or~~ autologous; adult or pediatric) proposed to be performed by the applicant;

(ii) currently is certified as a National Marrow Donor Program; and

(iii) is located in the United States.

(C~~d~~) An applicant shall document that the existing ~~bone marrow transplantation~~BMT service meets the requirements of subsection (~~c~~B).

SECTION ~~8~~4. REQUIREMENTS FOR APPROVAL – ACQUISITION OF A BMT SERVICE BY A CANCER HOSPITAL

(1) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING BMT SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SECTION 3(5) AND THE DEPARTMENT INVENTORY.

(A) THE TOTAL NUMBER OF BMT SERVICES IS NOT INCREASED IN THE PLANNING AREA AS THE RESULT OF THE ACQUISITION.

(B) AS PART OF THE ACQUISITION OF THE BMT SERVICE, THE ACQUISITION OR REPLACEMENT OF THE CANCER HOSPITAL, OR FOR ANY OTHER REASONS, THE LOCATION OF THE BMT SERVICE SHALL BE LOCATED AT ITS PRIOR LOCATION OR IN SPACE WITHIN THE LICENSED CANCER HOSPITAL SITE.

(C) THE APPLICANT IS A CANCER HOSPITAL AS DEFINED BY THESE STANDARDS. THE APPLICANT SHALL, TO THE SATISFACTION OF THE DEPARTMENT, PROVIDE VERIFICATION OF PPS-EXEMPTION AT THE TIME OF APPLICATION, OR SHALL DEMONSTRATE COMPLIANCE WITH THE FOLLOWING TO THE SATISFACTION OF THE DEPARTMENT:

(I) THE APPLICANT, OR AN AFFILIATE OF THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE IN CONJUNCTION WITH A MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE CANCER CENTER, OR THE APPLICANT IS THE MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE CANCER CENTER.

(II) THE APPLICANT COMMITS TO PROVIDE EVIDENCE, SATISFACTORY TO THE DEPARTMENT, OF APPROVAL AS A PPS-EXEMPT HOSPITAL WITHIN THE TIME LIMITS SPECIFIED IN SUBSECTION (G).

(D) THE APPLICANT DEMONSTRATES THAT IT MEETS, DIRECTLY OR THROUGH ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT SERVICE, THE REQUIREMENTS SET FORTH UNDER SECTION 3(3), (6), (7), AND (8), AS APPLICABLE.

(E) THE APPLICANT AGREES TO EITHER HAVE A WRITTEN CONSULTING AGREEMENT AS REQUIRED BY SECTION 3(10) OR OBTAIN A DETERMINATION BY THE DEPARTMENT THAT SUCH AN AGREEMENT IS NOT REQUIRED BECAUSE THE EXISTING BMT STAFF, SERVICES, AND PROGRAM SUBSTANTIALLY WILL CONTINUE TO BE IN PLACE AFTER THE ACQUISITION.

(F) THE APPLICANT AGREES AND ASSURES TO COMPLY, EITHER DIRECTLY OR THROUGH ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT SERVICE, WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(G) IF THE APPLICANT DESCRIBED IN THIS SUBSECTION DOES NOT MEET THE TITLE XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS WITHIN 24 MONTHS AFTER RECEIVING CON APPROVAL UNDER THIS SECTION, THE DEPARTMENT MAY EXTEND THE 24-MONTH DEADLINE TO NO LATER THAN THE LAST SESSION DAY PERMITTED BY THE UNITED STATES CONSTITUTION FOR THE NEXT UNITED STATES CONGRESS IN SESSION AFTER THE EFFECTIVE DATE OF THESE STANDARDS. EXTENSION OF THE DEADLINE SHALL REQUIRE DEMONSTRATION BY THE APPLICANT, TO THE SATISFACTION OF THE DEPARTMENT, THAT THERE HAS BEEN PROGRESS TOWARD ACHIEVING THE CHANGES IN FEDERAL LAW AND REGULATIONS THAT ARE REQUIRED TO SECURE THE PPS EXEMPTION. IF THE APPLICANT FAILS TO MEET THE TITLE XVIII REQUIREMENTS FOR PPS EXEMPTION WITHIN THE 24-MONTH PERIOD, OR ITS POSSIBLE EXTENSION, THEN THE DEPARTMENT MAY EXPIRE THE CON GRANTED PURSUANT TO THIS SECTION ~~SHALL EXPIRE AUTOMATICALLY~~ AND WILL NOT BE SUBJECT TO FURTHER APPLICATIONS FOR ACQUISITION. HOWEVER, PRIOR TO THE FINAL DEADLINE FOR THE EXPIRATION OF THE CON, THE PRIOR HOLDER OF THE (CON/AUTHORIZATION) TO PROVIDE THE BMT SERVICE MAY APPLY FOR ACQUISITION OF THE SERVICE, PURSUANT TO ALL THE PROVISIONS OF THIS SECTION, EXCEPT FOR SUBSECTION (C).

2. APPLICANTS PROPOSING TO ACQUIRE AN EXISTING BMT SERVICE UNDER THIS SECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

Section 54. REVIEW STANDARDS FOR ~~Additional requirements for applications included in~~ comparative reviews

Sec. 45. (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 applicable. ~~to comparative reviews.~~

(~~3~~2) EACH APPLICATION IN A COMPARATIVE GROUP SHALL BE INDIVIDUALLY REVIEWED TO DETERMINE WHETHER THE APPLICATION HAS SATISFIED ALL 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. IF THE DEPARTMENT DETERMINES THAT TWO OR MORE COMPETING APPLICATIONS SATISFY ALL OF THE REQUIREMENTS FOR APPROVAL, THESE PROJECTS SHALL BE CONSIDERED QUALIFYING PROJECTS. THE DEPARTMENT SHALL APPROVE THOSE QUALIFYING PROJECTS WHICH, WHEN TAKEN TOGETHER, DO NOT EXCEED THE NEED, AS DEFINED IN SECTION 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWS, AND WHICH HAVE THE HIGHEST NUMBER OF POINTS WHEN THE RESULTS OF SUBSECTION (2) 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) OF THE CODE, BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWS, IN THE ORDER IN WHICH THE APPLICATIONS WERE RECEIVED BY THE DEPARTMENT, BASED ON THE DATE AND TIME STAMP PLACED ON THE APPLICATIONS BY THE CON ADMINISTRATIVE UNIT OF THE DEPARTMENT RESPONSIBLE FOR ADMINISTERING THE CON PROGRAM WHEN AN APPLICATION IS SUBMITTED.

~~(23)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed service will be located, on the date the application is submitted to the Department, as shown in the following schedule:~~

~~Number of BMT Transplant Services (adult or pediatric, as applicable) in HSA~~	~~Points Awarded~~
~~Two or more services~~	~~0~~
~~One service~~	~~2~~
~~No services~~	~~4~~

(2)(A)A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE STRAIGHT-LINE DISTANCE TO THE NEAREST EXISTING BMT SERVICE OF THE TYPE APPLIED FOR (ADULT OR PEDIATRIC), AS SHOW IN THE FOLLOWING SCHEDULE:

STRAIGHT-LINE DISTANCE TO NEAREST BMT SERVICE	Points Awarded
<75 MILES	0
75 – 150 MILES	1
>150 MILES	2

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed ~~hospital~~ site at which the proposed ~~bone marrow transplantation~~BMT service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume~~, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantationBMT service is proposed to be provided~~. Determine the licensed ~~hospital~~ site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed ~~hospital~~ site by 4.0. The result is the indigent volume factor ROUNDED TO THE NEAREST WHOLE NUMBER.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the NEAREST WHOLE NUMBER~~first decimal place~~, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total HOSPITAL charges expressed as a percentage, ROUNDED TO THE NEAREST WHOLE NUMBER, as determined by the Michigan Department of Community Health Medical Services Administration ~~pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual~~. The indigent volume data being used IN THIS SUBSECTION~~for rates~~ IS THE DATA IN THE MOST CURRENT DCH-MSA DISPROPORTIONATE SHARE HOSPITAL (DSH) REPORT ~~in effect~~ at the time

the application(S) is deemed submitted ~~will be used~~ by the Department ~~in determining the number of points awarded to each qualifying project~~.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the ~~bone marrow transplant~~BMT procedures will be performed and were referred for and received a ~~bone marrow transplant~~ BMT at an existing ~~bone marrow transplantation~~BMT service, and submits documentation from the existing ~~bone marrow transplantation~~BMT service(s) of these referrals.

(D) A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE NUMBER OF NECESSARY SUPPORT SERVICES/PERSONNEL AS IDENTIFIED IN SECTION 7 THAT THE APPLICANT HAS AVAILABLE ON-SITE ON THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT~~.~~, AS FOLLOWS: ~~THE APPLICANT SHALL EARN ONE (1) POINT EACH, UP TO A MAXIMUM OF ELEVEN (11) POINTS, FOR THE FOLLOWING:~~

(I) 24-HOUR BLOOD BANK SUPPORT, INCLUDING PHERESIS CAPABILITY, IRRADIATED BLOOD, PRODUCTS SUITABLE FOR CYTOMEGALOVIRUS-NEGATIVE TRANSPLANTS, AND BLOOD COMPONENT THERAPY.

(II) A PROCESSING AND CRYOPRESERVATION LABORATORY THAT MEETS THE STANDARDS OF THE FACT OR AN EQUIVALENT ORGANIZATION.

(III) ANATOMIC AND CLINICAL PATHOLOGY WITH COMPETENCY IN INTERPRETING PATHOLOGIC FINDINGS RELATED TO GRAFT-V-HOST DISEASE AND OTHER OPPORTUNISTIC INFECTIONS IN IMMUNO-COMPROMISED HOSTS.

(IV) THERAPEUTIC DRUG MONITORING.

(V) ONE OR MORE ATTENDING PHYSICIANS WITH FELLOWSHIP TRAINING, AND/OR AT LEAST 2 YEARS OF EXPERIENCE, IN PEDIATRIC AND/OR ADULT BMT, AS APPROPRIATE.

(VI) BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING PHYSICIANS IN ALL OF THE FOLLOWING AREAS: ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT VERSUS HOST DISEASE AND OTHER OPPORTUNISTIC DISEASES, INFECTIOUS DISEASES WITH EXPERIENCE IN IMMUNO-COMPROMISED HOSTS, AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY IRRADIATION.

(VII~~I~~) A TRANSPLANT TEAM COORDINATOR, WITH EXPERIENCE IN EVALUATING PRE AND POST BMT PATIENTS.

(VIII) NURSES WITH SPECIALIZED TRAINING IN PEDIATRIC AND/OR ADULT, AS APPROPRIATE, BMT, HEMATOLOGY/ONCOLOGY PATIENT CARE, ADMINISTRATION OF CYTOTOXIC THERAPIES, MANAGEMENT OF INFECTIOUS COMPLICATIONS ASSOCIATED WITH HOST-DEFENSE MECHANISMS, ADMINISTRATION OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND MANAGING IMMUNO-SUPPRESSED PATIENTS.

(IX) A PHARMACIST EXPERIENCED WITH THE USE OF CYTOTOXIC THERAPIES, USE OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND THE MANAGEMENT OF IMMUNO-SUPPRESSED PATIENTS.

(X) AN ACTIVE, FORMAL MULTI-DISCIPLINARY RESEARCH PROGRAM RELATED TO BMT.

(XI) A PROTECTIVE ENVIRONMENTAL INPATIENT UNIT FOR IMMUNO-SUPPRESSED PATIENTS THAT HAS AN ISOLATION POLICY, AN INFECTION CONTROL PLAN SPECIFIC TO THAT UNIT, AND AIR HANDLING SYSTEM CAPABLE OF PREVENTING NOSOCOMIAL INFECTIONS DISSEMINATED FROM CENTRAL HEATING AND COOLING SYSTEMS AND AMBIENT AIR.

THE APPLICANT SHALL RECEIVE POINTS, UP TO A MAXIMUM OF THREE (3), FOR THIS CRITERION ACCORDING TO THE FOLLOWING SCHEDULE:

NUMBER OF BMT SUPPORT PERSONNEL/SERVICES AVAILABLE	POINTS
ZERO OR ONE	0

TWO TO FIVE	1
SIX TO NINE	2
TEN OR ELEVEN	3

~~(3) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all 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. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWSof the Code, and which have the highest number of points when the results of subsection (2) 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, when 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, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the CON ADMINISTRATIVE UNIT OF THE DEPARTMENT RESPONSIBLE FOR ADMINISTERING THE CON PROGRAM WHEN AN APPLICATION IS SUBMITTED.Department in accordance with Rule 325.9123.~~

(4) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT AWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM THE CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED.~~No points will be awarded to an applicant under specific subsections of Section 4 if information presented is inconsistent with related information provided in other portions of the CON application.~~

Section ~~5~~6. Requirements for approval -- all applicants

Sec. ~~5~~6. 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~~ 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. ~~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 ~~6~~7. Project delivery requirements -- terms of approval ~~for all applicants~~

Sec. ~~6~~7. (1) An applicant shall agree that, if approved, the ~~bone marrow transplantation~~BMT service shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the ~~bone marrow transplantation~~BMT service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable, no later than the date the first ~~bone marrow transplant~~BMT procedure, allogeneic or autologous, is performed:

(i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(B) a cytogenetics and/or molecular genetic laboratory.

(C) a processing and cryopreservation laboratory that meets the standards of the ~~Foundation for Accreditation of Cell Therapy (~~FACT~~)~~ or an equivalent organization.

(D) ~~for a program that performs allogeneic transplants,~~ a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(E) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic AND~~or~~ autologous transplants).

(F) therapeutic drug monitoring.

(ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(A) a protective environmental ~~bone marrow transplant~~BMT inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(iii) An applicant shall establish and maintain written policies related to outpatient care for ~~bone marrow transplantation~~BMT patients, including at least the following:

(A) the ability to evaluate and provide treatment on a 24-hour basis.

(B) nurses experienced in the care of ~~bone marrow transplantation~~BMT patients.

(C) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(iv) A ~~bone marrow transplantation~~BMT service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(A) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. ~~If the bone marrow transplantationBMT service performs allogeneic transplants, t~~The team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(B) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate~~, bone marrow transplantation~~. ~~If a service performs allogeneic transplants, a~~At least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: ~~anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic or autologous transplants),~~ cardiology, gastroenterology~~, infectious diseases with experience in immuno-compromised hosts,~~ nephrology, psychiatry, pulmonary medicine, and CRITICAL CARE MEDICINE.~~radiation oncology with experience in total body irradiation, and an intensivist who is board-certified in critical care.~~

(D) ON-SITE AVAILABILITY OF BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING PHYSICIANS IN THE FOLLOWING AREAS: ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT VERSUS HOST DISEASE (SERVICES PERFORMING ALLOGENEIC TRANSPLANTS) AND OTHER OPPORTUNISTIC DISEASES (SERVICES PERFORMING ALLOGENEIC ~~OR~~AND AUTOLOGOUS TRANSPLANTS), INFECTIOUS DISEASES WITH EXPERIENCE IN IMMUNO-COMPROMISED HOSTS, AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY IRRADIATION.

(~~D~~E) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(~~E~~F) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(~~F~~G) nurses with specialized training in pediatric and/or adult, as appropriate, ~~bone marrow transplantation~~BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(~~G~~H) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(~~H~~I) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(~~I~~J) designated social services staff.

(~~J~~K) designated physical therapy staff.

(~~K~~L) data management personnel designated to the ~~bone marrow transplantation~~BMT service.

(~~L~~M) for an applicant performing pediatric ~~bone marrow transplants~~BMT, a child-life specialist.

(v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall include a patient ombudsman, who is familiar with the ~~bone marrow transplantation~~BMT service, but who is not a member of the transplant team.

(vi) An applicant shall develop and maintain patient management plans and protocols that include the following:

(A) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(C) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease ~~(allogeneic transplants)~~, and follow-up care.

(vii) An applicant shall establish and maintain a written quality assurance plan.

(viii) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(ix) An applicant shall participate actively in the education of the general public and the medical community with regard to ~~bone marrow transplantation~~BMT, and make donation literature available in public areas of the institution.

(x) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed ~~bone marrow transplantation~~BMT service.

(xi) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating ~~bone marrow transplant~~BMT patients.

(xii) A pediatric ~~bone marrow transplant~~BMT service shall maintain membership status in the Children's Oncology Group (COG).

(xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant

documents that the ~~bone marrow transplantation~~BMT service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

(xiv) 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) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult ~~bone marrow transplantation~~BMT service ~~that performs only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall perform at least ~~10~~30 TRANSPLANTS, OF WHICH AT LEAST 10 ARE allogeneic transplants, in the third 12-months of operation AND ANNUALLY THEREAFTER. ~~If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.~~

(B) A pediatric ~~bone marrow transplantation~~BMT service ~~that performs only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall perform at least 10 TRANSPLANTS, OF WHICH AT LEAST 5 ARE allogeneic transplants, in the third 12-months of operation. ~~If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation.~~ After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(C) A ~~bone marrow transplantation~~BMT service that performs both adult and pediatric ~~bone marrow transplants~~BMT shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(ii) 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, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated 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. In addition, an applicant shall report at least the following data for each patient:

(A) disease type.
(B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.
(C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.
(D) patient age, i.e., adult or pediatric as defined by these standards.
(E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
(F) relapse rates at 6-months, 1-year, and 5-years post-transplant.
(G) median follow-up, and patients lost-to-followup.
(H) cause(s) of death, if applicable.
(I) additional summary information, as applicable.

An applicant annually shall report for its ~~bone marrow transplantation~~BMT service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from ~~bone marrow transplant~~BMT.

(iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the ~~bone marrow transplantation~~BMT service.

(iv) An applicant, to assure that the ~~bone marrow transplantation~~BMT service(s) will be utilized by all segments of the Michigan population, shall:

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

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; 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.

(v) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform ~~either allogeneic or~~ autologous procedures~~, whichever was not performed initially by the applicant~~.

(vi) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the ~~bone marrow transplantation~~BMT service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(vii) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(2) The agreements and assurances required by this section~~, as applicable, shall be in the~~ shall be in the form of a certification agreed to by the applicant or its authorized agent. ~~authorized by the governing body of the applicant or its authorized agent.~~

Section ~~7~~8. Documentation of projections

Sec. ~~7~~8. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. THE APPLICANT SHALL USE RELEVANT AND UNDUPLICATED DATA FOR PATIENTS IN THE SAME PLANNING AREA AS THE PROPOSED BMT SERVICE, WHICH ARE VERIFIABLE FROM THE MOST RECENT STATEWIDE TUMOR REGISTRY. THE APPLICANT SHALL ONLY INCLUDE NEW CANCER CASES THAT ARE APPROPRIATE FOR REFERRAL FOR BONE MARROW TRANSPLANTATION SERVICES AND FROM THE AGE GROUPING OF PATIENTS BASED ON THE TYPE OF SERVICE TO BE OFFERED. This specification of projections shall include aN ~~description of the data source(s) used,~~ assessment~~s~~ of the accuracy of ~~these data~~PROJECTIONS, and OF the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

~~**Section 8. Requirements for approval – acquisition of a bone marrow transplantation service by a cancer hospital**~~

~~(1) An applicant proposing to acquire an existing bone marrow transplantation service shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with section 3(5) and the department inventory.~~

~~(a) The total number of bone marrow transplantation services is not increased in the planning area as the result of the acquisition.~~

~~(b) As part of the acquisition of the bone marrow transplantation service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the bone marrow transplantation service shall be located at its prior location or in space within the licensed cancer hospital site.~~

~~(c) The applicant is a cancer hospital as defined by these standards. The applicant shall, to the satisfaction of the Department, provide verification of PPS-exemption at the time of application, or shall demonstrate compliance with the following to the satisfaction of the Department:~~

~~(i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center recognized by the National Cancer Institute in conjunction with a Michigan university that is designated as a comprehensive cancer center, or the applicant is the Michigan university that is designated as a comprehensive cancer center.~~

~~(ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a PPS-exempt hospital within the time limits specified in subsection (g).~~

~~(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, the requirements set forth under section 3(3), (6), (7), and (8), as applicable.~~

~~(e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing bone marrow transplantation staff, services, and program substantially will continue to be in place after the acquisition.~~

~~(f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, with all applicable project delivery requirements.~~

~~(g) If the applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS within 24 months after receiving CON approval under this section, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the next United States Congress in session after the effective date of these standards. Extension of the deadline shall require demonstration by the applicant, to the satisfaction of the Department, that there has been progress toward achieving the changes in federal law and regulations that are required to secure the PPS exemption. If the applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible extension, then the CON granted pursuant to this section shall expire automatically and will not be subject to further applications for acquisition. However, prior to the final deadline for the expiration of the CON, the prior holder of the (CON/authorization) to provide the bone marrow transplantation service may apply for acquisition of the service, pursuant to all the provisions of this section, except for subsection (c).~~

~~2. Applicants proposing to acquire an existing bone marrow transplantation service under this section shall not be subject to comparative review.~~

Section 9. Health Service Areas

Sec. 9. Counties assigned to each health service area 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 10. Department Inventory of ~~Bone Marrow Transplantation~~BMT Services

Sec 10. The Department shall maintain, and provide on request, a listing of the Department Inventory of ~~bone marrow transplantation~~BMT services.

Section 11. Effect on prior CON Review Standards; comparative reviews

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Transplantation Services pertaining to ~~bone marrow transplantation~~BMT services approved by the CON Commission on ~~December 12, 2006~~SEPTEMBER 16, 2008 and effective on ~~March 8, 2007~~NOVEMBER 13, 2008.

(2) Projects reviewed under these standards shall be subject to comparative review.

Michigan Department of Community Health (MDCH or Department)
MEMORANDUM
Lansing, MI

Date: March 16, 2010

TO: Irma Lopez

FROM: Kasi Hunziger

RE: Summary of Public Hearing Comments on Heart/Lung and Liver Transplantation Standards and MDCH Policy Staff Analysis

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the Heart/Lung and Liver (HLL) Transplant Standards at its December 9, 2009 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed HLL Services Standards on February 10, 2010. 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 two organizations and is summarized as follows:

1. *Dennis McCafferty, The Economic Alliance of Michigan:*
   The Economic Alliance of Michigan supports the proposed changes to the HLL standards as the current limit of three HLL programs in Michigan is being maintained. They feel that given the fixed supply of organs available for transplant that the current limit of three programs in the state meets the access, cost, and quality needs of the community. Additionally, they go on to state that given the findings by the Department of there only being two programs in operation that Spectrum's application to open a third program in west Michigan will help address any geographic access issues.

2. *Robert Meeker, Spectrum Health:*
   Spectrum Health supports the proposed changes to the HLL Transplant standards with regard to maintaining the current cap of three programs and the streamlined project delivery requirements. However, they do suggest one proposed change to the standards which would be to modify the definition of "initiate."

   Spectrum states that the current definition of the term initiate as applied to transplant service specifies that a new program must perform the first transplant procedure within 18 months of approval. They state that this is

far too short of a time frame. They believe it is too short because 1) transplant patients are often listed on waiting lists for an average of 16 months and 2) that a new transplant program cannot begin to list patients until all UNOS requirements are met, including that of having specialized personnel available at the center in which it can cake a year or more to recruit these personnel. Spectrum requests that the implementation period for a new heart and lung transplant program be extended to 24 months instead of the current 18 months. Alternatively, they state that initiation could be defined as performing the first transplant procedure within 18 months of UNOS certification.

Staff Analysis and Recommendations

The only new issue raised during the public hearing was that of modifying the definition of the term “initiate” or “implement.” This issue was not brought forward during the SAC meetings. The Department sees no need to make this change to the proposed language as the administrative rules (325.9403) already allow for a possible extension of an additional 6 months.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR HEART/LUNG AND LIVER TRANSPLANTATION 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 heart/lung or liver transplantation services.~~ THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, HEART/LUNG AND LIVER TRANSPLANTATION ~~IS A~~ARE COVERED CLINICAL SERVICES. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE, BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

(2) ~~Heart/lung or liver transplantation is a covered clinical service for purposes of Part 222 of the Code.~~

~~(3)~~ For purposes of Part 222 a separate CON is required for heart/lung or liver transplantation services. A CON issued for a heart/lung transplantation service includes a service that performs heart, heart/lung, or lung transplant procedures and a separate CON is not required to begin performing any of these procedures if one or more are not performed initially.

~~(4) The Department shall use sections 3, 4, 5, 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 sections 7, 8, 9, and 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) As used in these standards:

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

(b) "Comparative group" means the applications that have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

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

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

(e) "Health service area" or "HSA" means the geographic area set forth in Section ~~129~~.

~~(f) "Implementation plan" means a plan that documents how a proposed transplantation service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify: (i) each component or activity necessary to begin performing the proposed transplantation service, including but not limited to, the development of physical plant requirements such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff; (ii) the time table for completing each component or activity specified in subsection (i); and (iii) if the applicant previously has been approved for a transplantation service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be~~

~~made to ensure that the proposed service can be initiated and provided on a regular basis.~~

(~~g~~F) "Initiate" or "implement" ~~for purposes of these standards,~~ means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2)~~, if authorized by the Department.~~

(~~h~~G) "Licensed site" means ~~either (i) in the case of a single site hospital,~~ the location of the ~~facility~~ 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 unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.~~

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

(~~j~~I) ~~"OPO" or "Organ Procurement Organization" OR "OPO" means an organ procurement organization as defined by Title 42, Part 485.302.~~ "ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK" OR "OPTN" MEANS THE ORGANIZATION CONTRACTED BY THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES TO OPERATE THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(~~k~~J) ~~"OPTN" or "Organ Procurement and Transplantation Network" OR "OPTN" means the organization contracted by the federal Department of Health and Human Services to operate the organ procurement and transplantation network.~~ "ORGAN PROCUREMENT ORGANIZATION" OR "OPO" MEANS AN ORGAN PROCUREMENT ORGANIZATION AS DEFINED BY CFR TITLE 42, PART 485.302.

(~~l~~K) "Pediatric" means~~, for purposes of these standards,~~ any patient less than 15 years of age or any patient with congenital anomalies related to the proposed transplantation service.

(~~m~~L) "Planning area" means the state of Michigan.

(~~n~~M) "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.

(~~o~~N) "Survival rate" means~~, for purposes of these standards,~~ the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

~~(pO) "Transplant and Health Policy Center" means the statewide organization which studies issues regarding organ transplantation and other emerging health care technologies and operates the organ transplant registry.~~

~~(q) "Transplant support program" means, for purposes of these standards, a program where a hospital providing a transplantation service has a written agreement with one or more hospitals to coordinate the care of transplant patients residing outside the HSA in which the hospital providing the transplantation service is located in order that patients may receive transplant-related services, to the maximum extent practical, at the hospital with which the agreement is written. The program shall be active on the date an application is submitted to the Department having accepted potential transplant~~

~~recipient(s) into the program.~~

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

Section 3. Requirements for ~~approval --~~ all applicants

Sec. 3. (1) An applicant proposing to perform either a heart, heart/lung, ~~or~~ lung or liver transplantation service shall demonstrate that it offers all of the following services or programs:

(a) operating rooms;
(b) anesthesiology;
(c) microbiology and virology laboratory;
(d) continuous availability, either on-site or on-call, of:
(i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear medicine; and
(ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.
(e) dialysis;
(f) infectious disease;
(g) inpatient-outpatient social work;
(h) inpatient-outpatient psychiatry/psychology;
(i) clinical research;
(j) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization THAT IS AN APPROVED MEMBER OF THE OPTN, either on-site or through written agreement;
(k) other support services, as necessary, such as physical therapy and rehabilitation medicine;
(l) continuous availability of anatomic and clinical pathology and laboratory services including clinical chemistry, immuno-suppressive drug monitoring and tissue typing;
(m) continuous availability of red cells, platelets, and other blood components;
(n) an established organ donation protocol, with brain death protocol, consistent with applicable Michigan law; and
(o) a written TRANSPLANT agreement with Michigan's federally designated ~~organ procurement organization (~~OPO~~)~~ to promote organ donation at the applicant hospital(s).

(2) An applicant must provide~~, at the time the CON application is submitted,~~ an implementation plan for the proposed transplantation service. IMPLEMENTATION PLAN MEANS A PLAN THAT DOCUMENTS HOW A PROPOSED TRANSPLANTATION SERVICE WILL BE INITIATED WITHIN THE TIME PERIOD SPECIFIED IN THESE STANDARDS OR THE CON RULES. AT A MINIMUM, THE IMPLEMENTATION PLAN SHALL IDENTIFY:

(~~I~~A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE PROPOSED TRANSPLANTATION SERVICE, INCLUDING BUT NOT LIMITED TO, THE DEVELOPMENT OF PHYSICAL PLANT REQUIREMENTS SUCH AS AN INTENSIVE CARE UNIT CAPABLE OF TREATING IMMUNO-SUPPRESSED PATIENTS, EQUIPMENT ACQUISITIONS, AND RECRUITMENT AND EMPLOYMENT OF ALL PHYSICIAN AND SUPPORT STAFF;

(~~II~~B) THE TIMETABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN SUBSECTION (I); AND

(~~III~~C) IF THE APPLICANT PREVIOUSLY HAS BEEN APPROVED FOR A TRANSPLANTATION SERVICE FOR WHICH EITHER THE CON EXPIRED OR THE SERVICE DID NOT PERFORM A TRANSPLANT PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT CHANGES HAVE OR WILL BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE INITIATED AND PROVIDED ON A REGULAR BASIS.

(3) An application which proposes a joint sharing arrangement for a transplantation service which

involves more than one licensed site shall demonstrate all of the following:

(a) all licensed sites in the joint sharing arrangement are part of a single legal entity authorized to do business in Michigan;

(b) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;

(c) an applicant has designated a single licensed site where the transplant surgical procedure(s) will be performed, except that where an applicant proposes a joint sharing arrangement which involves both adult and pediatric transplant procedures, the applicant may designate a single licensed site where all adult transplant procedures will be performed and a single licensed site where all pediatric transplant procedures will be performed, if:

(i) both licensed sites are part of the joint sharing arrangement;

(ii) the same transplant coordinator will serve patients at both licensed sites;

(iii) laboratory procedures related to the proposed transplantation service will be performed at a single common laboratory operated by the applicant;

(iv) all physicians performing the proposed transplantation procedures at either licensed site are part of a common organizational entity (i.e., partnership, professional corporation, or medical school faculty); and

(v) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification.

(4) An applicant shall provide verification of Medicaid participation. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTY 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. ~~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.~~

(5) AN APPLICATION WHICH PROPOSES A JOINT SHARING ARRANGEMENT FOR A HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANTATION SERVICE WHICH INVOLVES MORE THAN ONE LICENSED SITE, WHERE THE LICENSED SITES IN THE JOINT SHARING ARRANGEMENT ARE NOT PART OF A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN MICHIGAN, SHALL NOT BE REQUIRED TO MEET SECTION 4(1) OR 5(1) OF THESE STANDARDS, IF AN APPLICANT CAN DEMONSTRATE ALL OF THE FOLLOWING:

(I) EACH LICENSED SITE IN THE JOINT SHARING ARRANGEMENT IS PARTY TO A WRITTEN JOINT VENTURE AGREEMENT AND EACH LICENSED SITE HAS JOINTLY FILED AS THE APPLICANT FOR THE CON;

(II) ALL LICENSED SITES IN THE JOINT SHARING ARRANGEMENT ARE GEOGRAPHICALLY CLOSE ENOUGH SO AS TO FACILITATE COST-EFFECTIVE SHARING OF RESOURCES;

(III) THE APPLICATION CONTAINS A FORMAL PLAN FOR THE SHARING OF SERVICES, STAFF AND ADMINISTRATIVE FUNCTIONS RELATED TO THE TRANSPLANTATION SERVICE, INCLUDING BUT NOT LIMITED TO: PATIENT REVIEW, PATIENT SELECTION, DONOR ORGAN RETRIEVAL AND PATIENT CARE MANAGEMENT;

(IV) AN APPLICANT HAS DESIGNATED A SINGLE LICENSED SITE WHERE ALL OF THE ADULT TRANSPLANTATION PROCEDURES WILL BE PERFORMED AND A SINGLE LICENSED SITE WHERE ALL OF THE PEDIATRIC TRANSPLANTATION PROCEDURES WILL BE PERFORMED, PROVIDED THAT BOTH LICENSED SITES ARE PART OF THE JOINT SHARING ARRANGEMENT;

(V) THE LICENSED SITE AT WHICH THE PEDIATRIC TRANSPLANTATION SERVICE WILL BE PROVIDED SHALL HAVE ADMITTED OR DISCHARGED AT LEAST 7,000 PEDIATRIC PATIENTS DURING THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT;

(VI) THE LICENSED SITE THAT IS DESIGNATED AS THE SITE AT WHICH ADULT PROCEDURES WILL BE PERFORMED IS AUTHORIZED UNDER FORMER PART 221 OR PART 222, AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT, TO PERFORM ADULT

HEART OR HEART/LUNG OR LUNG OR LIVER TRANSPLANTATION SERVICES;

(VII) THE APPLICANT SHALL AGREE THAT THE TWO LICENSED SITES WILL JOINTLY APPLY TO PERFORM TRANSPLANTATION PROCEDURES UNDER THE SAME OPTN CERTIFICATION; AND

(VIII) THE APPLICANT PROJECTS A MINIMUM OF 12 ADULT AND 10 PEDIATRIC HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANTATION PROCEDURES IN THE SECOND 12-MONTHS OF OPERATION FOLLOWING THE DATE ON WHICH THE FIRST HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANT PROCEDURE IS PERFORMED, AND ANNUALLY THEREAFTER.

Section 4. Additional requirements for ~~applicants seeking approval to provide~~ heart, ~~or~~ heart/lung or lung transplantation services

Sec. 4. (1) Approval of an application proposing to provide heart, ~~or~~ heart/lung or lung transplantation services shall not result in more than three (3) heart, ~~or~~ heart/lung or lung transplantation services in the planning area. In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 43(5) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 43(5) of these standards, an applicant for a heart, ~~or~~ heart/lung or lung transplantation service shall project a minimum of 12 heart, ~~or~~ heart/lung or lung transplantation procedures annually in the second 12-months of operation following the date on which the first heart, ~~or~~ heart/lung or lung transplant procedure is performed and annually thereafter.

(3) An applicant proposing to provide heart, ~~or~~ heart/lung or lung transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

(4) An applicant proposing to provide a heart, ~~or~~ heart/lung or lung transplantation service shall demonstrate that it offers all of the following services or programs:

(a) a cardiovascular medical/surgical program that includes at least the following: (i) an open heart surgery service that performs at least 300 adult and/or 100 pediatric procedures annually, as applicable; and (ii) a cardiac catheterization service that performs at least 500 adult and/or 250 pediatric cardiac catheterizations and coronary arteriograms annually, as applicable, and has the capability to perform these procedures on an emergency basis.

(b) continuous availability, either on-site or on-call, of angiography services;

(c) an intensive care unit with 24-hour per day on-site physician coverage;

(d) continuously available coagulation laboratory services; and

(e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on demand.

~~(5) An application which proposes a joint sharing arrangement for a heart or heart/lung or lung transplantation service which involves more than one licensed site, where the licensed sites in the joint sharing arrangement are not part of a single legal entity authorized to do business in Michigan, shall not be required to meet Section 4(1) of these standards, if an applicant can demonstrate all of the following:~~

~~(i) each licensed site in the joint sharing arrangement is party to a written joint venture agreement and each licensed site has jointly filed as the applicant for the CON;~~

~~(ii) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;~~

~~(iii) the application contains a formal plan for the sharing of services, staff and administrative functions related to the transplantation service, including but not limited to: patient review, patient selection, donor organ retrieval and patient care management;~~

~~(iv) an applicant has designated a single licensed site where all of the adult transplantation~~

~~procedures will be performed and a single licensed site where all of the pediatric transplantation procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;~~

~~(v) the licensed site at which the pediatric transplantation service will be provided shall have admitted or discharged at least 7,000 pediatric patients during the most recent 12-month period for which verifiable data are available to the Department;~~

~~(vi) the licensed site that is designated as the site at which adult procedures will be performed is authorized under former Part 221 or Part 222, at the time the application is submitted to the Department, to perform adult heart or heart/lung or lung transplantation services;~~

~~(vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification; and~~

~~(viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung transplantation procedures in the second 12-months of operation following the date on which the first heart or heart/lung or lung transplant procedure is performed, and annually thereafter.~~

Section 5. Additional requirements for ~~applicants seeking approval to provide~~ liver transplantation services

Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not result in more than three (3) liver transplantation services in the planning area. IN EVALUATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICATION SUBMITTED OR A CERTIFICATE APPROVED PURSUANT TO SECTION 3(5) OF THESE STANDARDS SHALL BE CONSIDERED AS A SINGLE SERVICE.

(2) EXCEPT FOR AN APPLICATION PURSUANT TO SECTION 3(5) OF THESE STANDARDS, an applicant for a liver transplantation service shall project a minimum of 12 liver transplantation procedures annually in the second 12-months of operation following the date on which the first liver transplant procedure is performed, and annually thereafter.

(3) An applicant proposing to provide liver transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

(4) An applicant proposing to provide a liver transplantation service shall demonstrate that it offers all of the following services or programs:

(a) continuous availability, either on-site or on-call, of angiography services;
(b) an intensive care unit with 24-hour per day on-site physician coverage;
(c) endoscopic retrograde cholangiopancreatography (ERCP) availability;
(d) percutaneous cholangiogram availability;
(e) percutaneous liver biopsy capability;
(f) a rapid blood infusion system;
(g) hemoperfusion; and
(h) a rapid red blood cell (RBC) blood saver system.

Section 6. REVIEW STANDARDS FOR ~~Additional requirements for applications included in~~ comparative reviews

Sec. 6. (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. ~~applicable to comparative reviews.~~

(2)(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform

Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the Michigan Compiled Laws. The number of points awarded shall be calculated by dividing the number of deaths reported to the OPO by the total number of eligible deaths reported to the Department and multiplying the product by 4. The maximum number of points that can be awarded under this subsection is 4. An applicant shall provide, in the application at the time it is submitted to the Department, documentation of the total number of eligible deaths at the licensed site at which the proposed transplantation service will be provided, for the most recent year for which the Department has verifiable data.

(b) A qualifying project will have points awarded based on the number of transplantation services of the type proposed, both operating and CON approved, but not yet operational, in the health service area in which the proposed program will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of Transplant Programs in HSA	Points Awarded
Two or more programs	0
One program	2
No programs	4

(c) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed ~~hospital~~ site at which the proposed heart/lung or liver transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume~~, rounded to the nearest whole number, for each licensed hospital site at which a heart/lung or liver transplantation service is proposed to be provided~~. Determine the licensed ~~hospital~~ site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed ~~hospital~~ site by 4.0. The result is the indigent volume factor ROUNDED TO THE NEAREST WHOLE NUMBER.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, TO THE NEAREST WHOLE NUMBER~~to the first decimal place~~, is the number of points that will awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total HOSPITAL charges expressed as a percentage, ROUNDED TO THE NEAREST WHOLE NUMBER, as determined by the Michigan Department of Community Health Medical Services Administration ~~pursuant to Chapter VIII of the Medical Assistance Hospital Program Manual~~. The indigent volume data being used IN THIS SUBSECTION ~~for rates~~ IS THE DATA IN THE MOST CURRENT DCH-MSA DISPROPORTIONATE SHARE HOSPITAL (DSH) REPORT~~in effect~~ at the time the application(S) is deemed submitted ~~will be used~~ by the Department ~~in determining the number of points awarded to each qualifying project~~.

(d) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed ~~hospital~~ site at which the heart/lung or liver transplant procedures will be performed and were referred for and received a heart/lung or liver transplant at an existing heart/lung or liver transplantation service, and submits documentation from the existing heart/lung or liver transplantation service(s) of these referrals.

(3) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all 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. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The

Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, 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, in the order in which the applications were received by the Department, based on the date and time stamp placed on the application ~~for~~ BY THE CON ~~form (form T-150-G-1.01 or any subsequent replacement form) by the Division of Health Facility Development (or the~~ administrative unit of the Department responsible for administering the CON program~~)~~ when an application is submitted.

(4) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT REWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED.~~No points will be awarded to an applicant under specific subsections of Section 6 if information presented in Section 6 is inconsistent with related information provided in other portions of the CON application.~~

Section 7. Project delivery requirements -- terms of approval ~~for all applicants~~

Sec. 7. (1) An applicant shall agree that, if approved, the services shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable:

(i) The applicant shall perform the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall comply AND REMAIN A FUNCTIONALLY ACTIVE PROGRAM with THE ~~applicable~~ OPTN AND ITS BY-LAWS AND POLICIES.

(A) THE APPLICANT SHALL COMPLY WITH THE~~and Medicare~~ CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS) STANDARDS AND SHALL BECOME MEDICARE APPROVED WITHIN FIVE YEARS OF IMPLEMENTATION.~~requirements~~OF SERVICES.

(B) THE APPLICANT MUST BE IN GOOD STANDING WITH THE OPTN.

(iii) The transplantation service shall have a transplant team leader and coordinator.

(iv) The applicant shall have patient management plans and protocols that include the following: (A) therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service; and (C) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(v) The applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(vi) An applicant shall actively participate in the education of the general public and the medical community with regard to transplantation, and will make organ donation literature available in public areas of the institution.

(vii) The applicant shall establish and maintain an active, formal multi-disciplinary research program

related to the proposed transplantation service.

(viii) The applicant's education and research program related to transplantation shall be subject to external peer review.

(ix) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant. ~~and on its transplant recipients and shall participate in the statewide transplantation registry operated by the Transplant and Health Policy Center and other national and international registries applicable to the transplantation service.~~ THE APPLICANT SHALL ALSO MAINTAIN A REGISTRY OF PATIENTS LISTED FOR A TRANSPLANT AND FOR TRANSPLANT RECIPIENTS AS REQUIRED BY THE FEDERAL OPTN.

(x) 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, patient survival rates at both 12 and 24 months following the transplant procedure, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated 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.

(xi) The applicant, to assure that the transplantation service(s) will be utilized by all segments of the Michigan population, shall:

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

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; 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) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiii) The transplantation service must operate, or have a written agreement with, a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(xiv) 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) Compliance with the Uniform Anatomical Gift Law, ~~Act No. 186 of the Public Acts of 1986, being~~PURSUANT TO MCL Section 333.10101 et seq. of the Michigan Compiled Laws.

(2) The agreements and assurances required by this section, ~~and sections 8, 9, and 10,~~ as applicable, shall be in the form of a certification ~~authorized by the governing body of~~ AGREED TO BY the applicant or its authorized agent.

~~**Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver transplantation services**~~

~~Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:~~

~~(a) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed transplantation service;~~

~~(b) organ preservation capability;~~

~~(c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;~~

~~(d) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;~~

~~(e) a cyclosporine assay laboratory with results available on the same day;~~

~~(f) an immunologic monitoring laboratory;~~

~~(g) a specialized inpatient transplantation unit;~~
~~(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient and managing immuno-suppressed patients.~~
~~(i) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;~~
~~(j) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients; and~~
~~(k) a multi-disciplinary transplant recipient evaluation committee.~~

~~(2) An applicant shall agree that the transplantation service shall be staffed with qualified adult and pediatric, as applicable, transplant surgeon(s) and transplant physician(s). For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the surgeon(s) and physician(s) if they meet the requirements for certification by Medicare or the OPTN. However, the applicant may submit and the Department may accept other evidence that the surgeon(s) and physician(s) are qualified.~~

~~Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung transplantation services~~

~~Sec. 9. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be staffed and provided by at least the following:~~
~~(a) cardiologists or surgeons trained in endocardial biopsy;~~
~~(b) cardiologists and surgeons trained in immunosuppression techniques;~~
~~(c) both adult and pediatric, as appropriate, cardiologists and surgeons;~~
~~(d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants in animals in a setting simulating the human situation;~~
~~(e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing a recipient operation;~~
~~(f) a pathologist capable of diagnosing rejection on endocardial biopsies; and~~
~~(g)an anesthesiologist trained in open heart surgery.~~
~~(2) An applicant must demonstrate heart transplant patient survival rates at one year and two years after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must demonstrate patient survival rates at one and two years after transplantation of no less than the national average survival rate for the specific transplant type for the most recent year for which data is published by the OPTN.~~

~~Section 10. Additional terms of approval -- applicants proposing liver transplantation services~~

~~Sec. 10. (1) An applicant shall agree that the liver transplantation service will be staffed and provided by at least the following:~~
~~(a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals in a setting simulating the human situation;~~
~~(b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy, repair of biliary strictures, and Porto systemic shunts;~~
~~(c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical staff;~~
~~(d) a pathologist capable of diagnosing hepatic rejection;~~
~~(e) anesthesiologist(s) trained in liver transplantation;~~
~~(f) two liver transplant surgical teams, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in preparation for liver implantation; and~~
~~(g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available~~

~~for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver transplant recipient operation; and, a veno-venous bypass system which does not require heparin.~~

~~(2) The applicant shall establish and maintain all of the following:~~
~~(a) nuclear HID biliary scan availability;~~
~~(b) a continuously available coagulation laboratory; and~~
~~(c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of plasma on demand.~~

~~(3) An applicant must demonstrate patient survival rates at one year and two years after transplantation of no less than the national average survival rate for the most recent year for which data is published by the OPTN.~~

Section ~~11~~8. Documentation of projections

Sec. ~~11~~8. An applicant required to project volumes of service under sections 4 or 5 shall 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 if the projections are reasonable.

Section ~~12~~9. Health Service Areas

Sec. ~~12~~9. Counties assigned to each of the health service areas 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 ~~13~~10. Effect on prior CON Review Standards; comparative reviews

Sec. ~~13~~10. (1) These CON review standards supersede and replace the CON Review Standards for ~~Extrarenal Transplantation~~ FOR HEART/LUNG AND LIVER TRANSPLANTATION Services approved by the CON Commission on ~~June 4, 1997~~MARCH 9, 2004 and effective on ~~July 26, 1997~~JUNE 4, 2004.

(2) Projects reviewed under these standards shall be subject to comparative review.

Michigan Department of Community Health (MDCH or Department)
MEMORANDUM
Lansing, MI

Date: March 16, 2010

TO: Irma Lopez

FROM: Michael Berrios

RE: Summary of Public Hearing Comments on Magnetic Resonance Imaging Standards (MRI) and MDCH Policy Staff Analysis

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the MRI Standards at its December 9, 2009 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRI Standards on February 10, 2010. 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 nine organizations and is summarized as follows:

1. *Barbara Jackson, Blue Cross Blue Shield Michigan (BCBSM/BSN)*
   Blue Cross Blue Shield Michigan (BCBSM/BSN) continue to oppose many proposed exemptions to CON review standards, since they believe multiple exceptions weaken the standards as a whole and have the potential to increase health care service delivery costs.

   BCBSM does not support the proposed language that allows replacing mobile MRI units with fixed MRI units for free-standing for-profit imaging centers that provide at least 25% of their service to Medicaid-covered patients. There are many questions concerning the validity of these proposals. The additional capacity would be in direct competition with existing hospital-based not-for-profit MRI units, including units for patients having coverage other than Medicaid.

2. *Sean Gehle, Ascension Health*
   Ascension Health opposes the proposed language change to the MRI standards. Ascension believes that making an exception in the standards will negatively impact private, for-profit providers. It also opposes the creation of a different and lower threshold for for-profit entities vis-à-vis non-profit providers to convert a mobile MRI to fixed, as it believes it will establish a dangerous precedent in the broader CON context. It also

questions what legal basis exists around the creation of different standards that differentiate providers based on tax status within CON status.

3. *Amy Barkholz, Michigan Health and Hospital Association*
   MHA opposes the proposed language changes to the MRI Standards. MHA believes that the exception is unwarranted because data does not support the access concern, and believe that it will create an arbitrary financial incentive for excess and inappropriate utilization in order to qualify for another MRI.

4. *Eric Fischer, Detroit Medical Center*
   The Detroit Medical Center opposes the proposed amendments to the MRI standards. It believes that the amendment would effectively remove for-profit imaging centers from the need justification process and would create an uneven field of competition between for-profit and non-profit MRI services. It also has concerns as to the ability to monitor compliance of the 25% Medicaid/no charge requirement in the proposed amendment.

5. *Yahya M. Basha M.D., Basha Diagnostics*
   Basha Diagnostics withdraws its proposed amendment to the MRI standards, citing the current difficult economic times and its desire to work in cooperation with its colleagues and the Department. (See the attached correspondence)

6. *Dennis McCafferty, The Economic Alliance for Michigan*
   The Economic Alliance for Michigan opposes the proposed changes to the CON MRI standards. It asserts that the amendment would likely only benefit Basha Diagnostics and will open the door for more special requests for exemptions from CON standards in the future. It also questions Basha Diagnostic's claim that other area hospitals are lacking in their MRI services to indigent patients.

7. *Robert Meeker, Spectrum Health*
   Spectrum Health opposes the proposed changes to the MRI standards. Spectrum contends that there is no access concern and the amendment risks introducing excess MRI capacity into the system.

8. *David Williams, Williams Consulting Services LLC*
   Williams Consulting Services opposes the proposed modifications to the MRI standards. It believes that the proposed modifications would only benefit a select group of for-profit stakeholders at the expense of the non-profit hospitals and outpatient centers. Further, it states that the language poses complicated and unanswered questions as to monitoring and compliance.

9. *Janelle R. Spann, Michigan Resonance Imaging*
   Michigan Resonance Imaging opposes the proposed amendment to the MRI standards. It believes that there is no access concern and that the proposed amendment will create an arbitrary financial incentive for excess utilization. Furthermore, it contends that no quality or cost justification for the proposed language has been suggested.

Staff Analysis and Recommendations

The Department continues to question the necessity for the exemption provisions and supports removing this language from the proposed standards. There remain two administrative/technical changes that were originally proposed by the Department. These two changes reflect the Department's current practices and can easily be incorporated during the next review cycle. Therefore, the Department recommends that the proposed language in front of the Commission NOT be moved forward.

Basha Diagnostics, P.C.
specializing in medical imaging

February 15, 2010

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

Re: CON Standards for MRI Services

Dear Chairman Goldman,

I would like to take this opportunity to thank you and all of your colleagues on the Certificate of Need Commission for all of the care and attention you have given to the issues we have raised over the past year regarding access to MRI services for the underserved patient populations in our state. We especially would like to thank Dr. Sandler for all of the time he spent as the chair of the MRI workgroup and the extra effort he made in explaining this issue to the Commission at the many meetings during which this issue has been discussed. In addition, we would also like to specifically thank those CON Commissioners who took extra time out of their busy schedules to talk with us directly about this important issue and review the information and data we have provided to all of you over the past year, and especially those who felt strongly enough to speak up in support. We feel this issue has received a great deal of consideration and support from the Commission and we are truly grateful.

I am writing today to respectfully withdraw our request to the Commission to modify the CON Standards for MRI Services to allow the conversion of a mobile MRI host site to a fixed MRI unit upon maintaining a volume of 2,000 available adjusted procedures with a payer mix of at least 25% Medicaid and/or No Charge, more commonly referred to as the MRI Charity Care Proposal. Although our mission and belief in providing access to the underserved has not waivered, we recognize that the timing for these proposed changes may not yet be ideal. Everyone is struggling in this economy - patients, providers, and payers - putting a great deal of strain on all. Rather than moving forward with our proposal in an environment of increasing conflict and opposition, we would rather focus our attentions on working in the spirit of cooperation with our colleagues and the Department.

The support of the Commission in our efforts has been refreshing. Through your efforts on this issue you have shown that patient care and good public policy comes first in Certificate of Need. Rest assured that we will continue to reach out to those in need and continue to provide diagnostic services to the underserved populations in southeast

www.bashadiagnostics.com
30701 Woodward Ave., Suite LL Royal Oak, MI 48073 248.288.1600 Fax 248.288.2171
Radiology, Cardiology, & Neurology Testing

Basha Diagnostics, P.C.
specializing in medical imaging

Michigan and beyond, and look forward to working with others to continue improving access for our most vulnerable citizens. Again, we thank you for your time and attention to this issue and look forward to working with you in the future on such important policy matters.

Respectfully,

Yahya M. Basha, M.D., President
BASHA DIAGNOSTICS, P.C.

www.bashadiagnostics.com
30701 Woodward Ave., Suite LL Royal Oak, MI 48073 248.288.1600 Fax 248.288.2171
Radiology, Cardiology, & Neurology Testing

DiagnosticImaging.com

November 4, 2009
Diagnostic Imaging

ACR predicts 'access catastrophe' from 16% Medicare rate cuts

By James Brice

The American College of Radiology is predicting that imaging access will plunge and patient waiting times will soar from new Medicare Physician Fee Schedule rules that will cut Medicare payments for outpatient imaging by an estimated 16% next year.

Pressure from the Obama administration to restrain Medicare spending to offset the expected costs of expanded access through healthcare reforms was evident in rules that generally chipped away at high-cost services or well-paid physician specialists.

ACR officials expressed dismay at the new fee schedule rules, to be implemented Jan. 1.

"These shortsighted, unfounded, and misguided cuts will imperil community-based imaging, restrict access to cutting-edge imaging scans, and delay diagnosis of cancers and other critical conditions, which may ultimately cost lives," said Dr. James Thrall, chair of the ACR board of chancellors, in a written statement. "Many hospitals are not equipped to handle the substantial influx of patients that could result from the inevitable closure of rural and suburban imaging facilities caused by these cuts."

Thrall's concern stems from new fee schedule rules that will raise the assumed utilization rate from 50% to 90% for a typical 45-hour work week for imaging equipment with an initial purchase price of more than $1 million. The increased utilization rate translates into lower reimbursement rates for outpatient imaging services.

To back up its opposition the 90% assumed utilization rate, the ACR referred to a recent Radiology Business Management Association survey finding that rural providers use scanners only 48% of office hours and that the national average is only 54%. The survey was conducted after a high utilization rate was proposed, however, a factor that may have biased how the imaging center managers responded to the questionnaire.

For the 2010 rules, CMS used practice expense data from the AMA's Physician Practice Information Survey, a move that led to payment cuts for CT and MRI. The ACR criticized the AMA survey for not questioning enough radiologists to assure accurate results. The costs of office-based radiology practices were significantly underrepresented, it said.

In combination, the higher utilization assumption and practice expense reimbursement adjustments produced an across-the-board average 16% cut to imaging providers. Reimbursement for some procedures, such as lung CT or spinal MRI, could fall more than 40%, according to the ACR.

According to the Access to Medical Imaging Coalition, which represents proimaging interests, the 2010 fee schedule will cut payments for nonhospital outpatient imaging by 48% for pelvic CT, 46% for MRI of the chest and spine, and 27% for selected cardiovascular imaging services. Cuts to cardiology services could affect up to two-thirds of cardiovascular

patients as some practices are forced to close, AMIC said in a release.

"These are catastrophic cuts when you talk about the combination of the practice expense and presumed utilization rate changes," said AMIC executive director Tim Trysla. "I know there is a lot of money being shifted to primary care physicians, but our biggest concern is these decisions are based on very limited information, largely from hospitals, to make these cuts."

BAD NEWS FOR CARDIOGISTS

Cardiologists were also displeased with CMS's use of the AMA practice survey. The American College of Cardiology blamed it for cuts from 10% to more than 40% for individual services. The reductions will be phased in over four years. Imaging-related cuts include a 36% cut for SPECT myocardial perfusion imaging, a 10% cut for transthoracic echocardiography with spectral and color flow Doppler, a 4% cut for coronary artery stenting, and a 5% cut for EKG.

The myocardial perfusion imaging rate cut will be implemented in January. CMS has also reduced payments for myocardial perfusion/SPECT studies by including wall motion and ejection fraction under a single billing code. The deep reimbursement cuts stem from a reduced physician work value and practice expense value, according to the ACC.

The 2010 fee schedule rules would be set in stone if this were an ordinary year, but with Congress fixated on reform, anything could happen in the next few weeks.

PENDING SGR CUTS

The imaging community will count on Congress to stave off the 21.2% across-the-board physician payment cut announced by CMS to adjust payments for its mandated sustainable growth rate requirement. Congress has intervened in each of the past seven years to delay proposed reductions. The accumulated effect of those individual decisions is reflected in the magnitude of the pending cut.

How Congress will respond this year is not easy to determine, according to Tom Greeson, a healthcare attorney with the law firm of Reed Smith. There have been attempts to deal with the so-called physician fix of the SGR mandate in reform legislation and in separate bills in the House and Senate.

The House reform bill would create two SGR update categories, Greeson said. The SGR increase in 2010 would be based on the Medicare Economic Index, a measure of inflation. It would be governed by two separate formulas in 2011, with primary and preventive services set at 2% above the index, and all other services, including diagnostic imaging, nuclear medicine, and radiation oncology, adjusted to 1% above the index, Greeson said.

Congress will also probably weigh in on the assumed utilization rate controversy. The Senate Finance Committee reform bill would increase the presumed utilization for advanced imaging technologies from the current 50% to 65%. The higher rates would be adopted incrementally between 2010 and 2013, according to Greeson. A required study of the higher rates will assess the reform's impact on Medicare costs and access to imaging services and in rural and underserved communities. It would have to be completed by 2013. Without follow-up congressional action, the presumed rate will increase to 75% in 2014.

The House bill would cut the presumed rate for MR, CT, PET, and nuclear medicine to 75%. That cut would be implemented in 2011.

ACCREDITATION TALK

Though still in the discussion stage, CMS invited comments on the 2010 final rules about the possibility of linking the 2012 accreditation requirement for high-tech medical imaging covered by Medicare and the antimarkup rule for

independent diagnostic testing facilities, including self-referred in-office imaging services.

CMS raised the possibility of requiring physicians who provide general supervision for imaging to also serve as the physician who bills Medicare for those services, Greeson said. The new accreditation rule will apply professional competency standards to the supervising physician.

"It is generally assumed that the accrediting organization will require physicians to demonstrate that they are qualified to perform the service," Greeson said. "CMS will not dictate what those qualifications are, but it expects the accrediting organizations to have credentialing requirements for the physicians who perform and provide general supervision for imaging services."

This article is part of a series

- 2010 Medicare fee schedule boosts equipment utilization rate
- Medicare cuts threaten small imaging facilities
- 2010 rate cuts could be worse than DRA, analysis finds
- ACR predicts 'access catastrophe' from 16% Medicare rate cuts

CancerNetwork | ConsultantLive | Diagnostic Imaging | Psychiatric Times
SearchMedica | Physicians Practice

CMPMedica
© 1996 - 2009 CMPMedica LLC, a United Business Media company
Privacy Statement - Terms of Service

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MAGNETIC RESONANCE IMAGING (MRI) 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. These standards are requirements for the approval of the initiation, expansion, replacement, relocation, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and 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 an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 13, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "MRI Service Utilization List," as of the date an application is deemed ~~complete~~ SUBMITTED by the Department.

(c) "Available MRI adjusted procedures" means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed ~~complete~~ SUBMITTED by the Department.

In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five host sites combined that is in excess of 7,000 MRI adjusted procedures.

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s).

(e) "Certificate of Need Commission" or "CON 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) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a procedure following use of a contrast agent or (ii) procedures performed both before and after the use of a contrast agent.

(h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age

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

(j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

(k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an application is submitted to the Department.

(l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI services.

(m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to be operated by the applicant.

(n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be operated by a central service coordinator that is approved to operate one or more mobile MRI units as of the date an application is submitted to the Department.

(o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(p) "Health service area" or "HSA" means the geographic areas set forth in Section 19.

(q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI services.

(r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does not provide or is not CON approved to provide fixed MRI services as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing fixed MRI service or the renewal of a lease.

(s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not received any MRI services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease.

(t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or more host sites.

The term does not include the acquisition of an existing mobile MRI service or the renewal of a lease.

(u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

(v) "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.

(w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI technology during surgical and interventional procedures within a licensed operative environment.

(x) "Licensed hospital site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

(z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 13.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section 12 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(bb) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an IRB. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 8(1).

(cc) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit at each host site.

(dd) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with an MRT unit.

(ee) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

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

(gg) "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.

(hh) "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.

(ii) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

(JJ) "NO CHARGE" MEANS AN MRI VISIT WHERE THE PATIENT IS NOT CHARGED A FEE FOR THE VISIT BY THE MRI SERVICE. THIS DOES NOT INCLUDE INPATIENT OR OTHER VISITS WHERE THE MRI VISIT IS INCLUDED IN A LARGER FEE BEING PAID BY A THIRD PARTY PAYER SUCH AS A DIAGNOSIS-RELATED GROUP (DRG) PAYMENT.

(~~jj~~KK) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

(~~kk~~LL) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.

(~~ll~~MM) "Planning area" means

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county.

(ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the proposed site is in a rural or micropolitan statistical area county.

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section 13(2)(d), the health service area in which all the proposed mobile host sites will be located.

(~~mm~~NN) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility, the attending doctor who is responsible for the house officer or resident that requested the MRI procedure.

(~~nn~~OO) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.

(~~oo~~PP) "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site of the MRI service or unit to be relocated.

(~~pp~~QQ) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit that does not involve either replacement of the MRI unit, as defined in Section 2(1)(pp)(i), or (ii) a change in the parties to the lease.

(~~qq~~RR) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or replacement of, the magnet resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change other than a change in the magnet that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

(~~rr~~SS) "Research scan" means an MRI scan administered under a research protocol approved by the applicant's IRB.

(~~ss~~TT) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation during the scan time and must be extracted from the unit to rescue the patient with additional sedation.

(~~tt~~UU) "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.

(~~uu~~VV) "Sedated patient" means a patient that meets all of the following:

(i) whose level of consciousness is either conscious-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 is monitored by mechanical devices while in the magnet.

(iii) who requires observation while in the magnet by personnel, other than employees routinely assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

(~~vv~~WW) "Site" means

(i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a location that is contiguous to the licensed hospital site or

(ii) in the case of a location that is not a licensed hospital site, a location at the same address or a location that is contiguous to that address.

(~~ww~~XX) "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.

(~~xx~~YY) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned.

(~~yy~~ZZ) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 13.

(~~zz~~AAA) "Upgrade an existing MRI unit" means any equipment change that

(i) does not involve a change in, or replacement of, the magnet; does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); and

(ii) involves a capital expenditure RELATED TO THE MRI EQUIPMENT of less than $750,000 in any consecutive 24-month period.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

(1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):
(a) The applicant is currently an existing host site.
(b) The applicant has received in aggregate, one of the following:
(i) At least 6,000 MRI adjusted procedures.
(ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:
(A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.
(B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.
(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:
(A) The proposed site is a hospital licensed under Part 215 of the Code.
(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the Department, is available.
(IV) AT LEAST 2,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF THE FOLLOWING:
(A) AT LEAST 25% OF THE MRI VISITS HAVE A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE.
(B) THE APPLICANT IS A FOR-PROFIT, FREESTANDING FACILITY.
(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.
(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.
(e) The applicant shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:
(a) Identify the proposed route schedule and procedures for handling emergency situations.
(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.
(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:
(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or
(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and
(c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):

(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures FROM THE AVAILABLE MRI ADJUSTED PROCEDURES LIST AND THE ADJUSTED PROCEDURES FROM THE MRI SERVICE UTILIZATION LIST, AS APPLICABLE, are from the most recently published available MRI adjusted procedures list as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements, as applicable:

(1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department:

(a) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI adjusted procedures per MRI unit.

(c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(2) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

(3) The replacement unit shall be located at the same site unless the requirements of the relocation section have been met.

(4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the proposed replacement equipment offers a significant technological improvement which enhances quality of care, increases efficiency, and reduces operating costs.

Section 5. Requirements to expand an existing MRI service

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:

(a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000 MRI adjusted procedures per MRI unit.

(c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(2) The additional fixed unit shall be located at the same site unless the requirements of the relocation section have been met.

Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)

Sec. 6. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall demonstrate the following:

(a) The existing MRI service and its unit(s) 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) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall demonstrate the following:

(a) The applicant currently operates the MRI service from which the unit will be relocated.

(b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(c) The proposed new site is in the relocation zone.

(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.

Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)

Sec 7. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section 12 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (a), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 12 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(C) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING FIXED MRI SERVICE AND ITS UNIT(S) THAT WAS INITIATED UNDER SECTION 3(2)(B)(IV) OF THESE STANDARDS, THE APPLICANT SHALL ALSO MEET THE REQUIREMENTS OF SECTION 3(2)(B)(IV).

(2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service shall demonstrate that the proposed project meets all of the following:

(a) The project will not change the number of MRI units at the site of the MRI service being acquired, subject to the applicable requirements under Section 6(2), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion Section, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of the replacement section have been met.

Section 8. Requirements to establish a dedicated research MRI unit

Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) Submit copies of documentation demonstrating that the applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

(2) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(3) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

Section 9. Requirements to establish a dedicated pediatric MRI unit

Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI 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 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:

(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 5 of these standards.

Section 10. Pilot program requirements for approval – applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 10. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate that it meets all of the following:

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

(2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site has an existing and operational surgical service and is meeting its minimum volume requirements pursuant to the CON Review Standards for Surgical Services.

(4) The applicant shall have experienced one of the following:
(a) at least 1,500 oncology discharges in the most recent year of operation; or
(b) at least 1,000 neurological surgeries in the most recent year of operation; or
(c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

(5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.

(6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this section unless the patient meets one of the following criteria:
(a) the patient has been admitted to an inpatient unit; or
(b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

(7) The approved IMRI unit will not be subject to MRI volume requirements.

(8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

(9) The provisions of Section 10 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 December 31, 2010.

Section 11. Requirements for all applicants

Sec. 11. 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. Project delivery requirements – terms of approval

Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:
(a) Compliance with these standards.
(b) Compliance with applicable safety and operating standards.
(c) Compliance with the following quality assurance standards:
(i) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.
(ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
(iii) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:
(A) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.
(B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
(C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.
(iv) An applicant shall document that the MRI team members have the following qualifications:

(A) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:

(1) The physician is licensed to practice medicine in the State of Michigan.

(2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, and the physician meets the requirements of subdivision (i), (ii), or (iii):

(i) Board certification by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology program completed by a physician in order to become board certified did not include at least two months of MRI training, that physician shall document that he or she has had the equivalent of two months of postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, that included two years of training in cross-sectional imaging and six months training in organ-specific imaging areas.

(iii) A practice in which at least one-third of total professional time, based on a full-time clinical practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

(3) The physician has completed and will complete a minimum of 40 hours every two years of Category in Continuing Medical Education credits in topics directly involving MR imaging.

(4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI scans annually.

(B) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have within 36 months of the effective date of these standards or the date a technologist is employed by an MRI service, whichever is later, special certification in MRI. If a technologist does not have special certification in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area of MRI services.

(C) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Science in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence that an MRI physicist/engineer is qualified appropriately.

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

(vi) 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) Compliance with the following terms of approval, as applicable:

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site. In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 8(1) or for an IMRI unit approved pursuant to Section 10.

(ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

(A) provide MRI services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment.

(B) maintain information by source of payment to indicate the volume of care from each source provided annually.

(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, operating schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9, or Section 10 shall be reported separately.

For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic.

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

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

(f) An applicant who is a central service coordinator shall notify the Department of any additions, deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the change(s) in host sites is made.

(2) An applicant for an MRI unit approved under Section 8(1) shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.

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

(b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 8.

(3) AN APPLICANT FOR AN MRI UNIT APPROVED UNDER SECTION 3(2)(B)(IV) SHALL AGREE TO CONTINUE TO PROVIDE AT LEAST 25% OF THE MRI VISITS WITH A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE DURING THE FIRST 12 MONTHS OF OPERATION AND ANNUALLY THEREAFTER FOR AT LEAST 10 YEARS.

(~~3~~4) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 13. MRI procedure adjustments

Sec. 13. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0.

(b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

(c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

(d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base value.

(e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

(f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base value.

(g) For each MRI visit that involves both a clinical and research scan on a single patient in a single visit, 0.25 shall be added to the base value.

(h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

(i) For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

(j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

(k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an MRI adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

Section 14. Documentation of actual utilization

Sec. 14. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "MRI Service Utilization List" as of the date an application is deemed ~~complete~~ SUBMITTED by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 15. The Department may elect to verify the data through on-site review of appropriate records.

Section 15. Methodology for computing the number of available MRI adjusted procedures

Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published “Available MRI Adjusted Procedures List,” as of the date an application is deemed ~~complete~~ SUBMITTED by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 13.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 8(1) and dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.

(ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures, from the host site routes utilized to meet the requirements of Section 3(2)(c), shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures utilized to meet the requirements of Section 5(1) shall be reduced by 8,000 and shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service as determined pursuant to Section 2(1)(c).

(c) Determine the number of available MRI adjusted procedures that each referring doctor may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring doctor made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each doctor, subtract any available adjusted procedures previously committed. The total for each doctor cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6 digits only).

(iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of doctors necessary to reach the 75 percent level.

(v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) The result shall be the "Available MRI Adjusted Procedures List."

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).

Section 16. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment, on a form provided by the Department in response to the applicant's letter of intent for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

(b) An applicant also shall submit, at the time the application is filed with the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each doctor for whom a signed and dated data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding physician commitments that were submitted at the time of application.

(c) If the required documentation for the doctor commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed ~~filed~~ SUBMITTED on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant's letter of intent that meets the requirements of each of the following, as applicable:

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 15, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(c) A committing doctor certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new or additional MRI unit, pursuant to Section 3, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

(ii) The MRI service or unit to which the data were committed has been in operation for at least 36 continuous months.

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) A final decision to disapprove an application is issued by the Director and the applicant does not appeal that disapproval or

(ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

(5) The Department shall not consider a data commitment from a committing doctor for available MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a doctor has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, the Department shall,

(a) if the applications were filed on the same designated application date, notify all applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI service shall not be considered in the review of any of the pending applications filed on the same designated application date until the doctor notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were filed on different designated application dates, consider the data commitment submitted in the application filed on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications filed on designated application dates subsequent to the earliest date that one or more committing doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in the review of the application(s) filed on the subsequent designated application date(s).

(6) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed ~~complete~~ SUBMITTED unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed ~~complete~~ SUBMITTED only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by the Department in this Section.

(7) In accordance with either of the following, the Department shall not consider a withdrawal of a signed data commitment

(a) during the 120-day period following the date on which the Department's review of an application commences.

(b) after a proposed decision to approve an application has been issued by the Department.

(8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor submits a written notice to the Department, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the requirements of subsection (7) also have been met.

Section 17. Lists published by the Department

Sec. 17. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated pediatric.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 15(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring doctor, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 12, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 12, and no data will be shown for that service on either list.

Section 18. Effect on prior CON Review Standards; Comparative reviews

Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 16, 2008~~ SEPTEMBER 10, 2009 and effective ~~November 13, 2008~~ NOVEMBER 5, 2009.

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

Section 19. Health Service Areas

Sec. 19. Counties assigned to each of the health service areas 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

APPENDIX A

CON REVIEW STANDARDS FOR MRI 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

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/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 the approval OF THE INITIATION, EXPANSION, RELOCATION, OR REPLACEMENT OF NEONATAL INTENSIVE CARE SERVICES/BEDS and THE delivery of NEONATAL INTENSIVE CARE services/BEDS ~~for all projects approved and Certificates of Need issued~~ under Part 222 of the Code ~~which involve neonatal intensive care services/beds~~. PURSUANT TO PART 222 OF THE CODE, NEONATAL INTENSIVE CARE SERVICES/BEDS

~~(2) The initiation, expansion, relocation, or replacement of neonatal intensive care services/beds~~ is a covered clinical service ~~for purposes of Part 222 of the Code~~.

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

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

~~(5) The Department shall use Section 10, as applicable, 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 these standards:

(a) "Acquisition of a NICU" means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.
(b) "Bassinet" means an unlicensed bassinet in the obstetrical or newborn service that provides care for the uncomplicated newborn.
(c) "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.
(d) "Code" means Act No. 368 of the Public Acts of 1978 as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
(e) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.
(f) "Department" means the Michigan Department of Community Health (MDCH).
(g) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.
(h) "Existing NICU beds" means the total number of all of the following:
(i) licensed hospital beds designated for NICU services;
(ii) NICU beds with valid CON approval but not yet licensed or designated;
(iii) NICU beds under appeal from a final decision of the Department; and

(iv) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision. The term includes those beds designated by the Department as special newborn nursery unit (SNNU) beds.

(i) "Expansion of NICU services" means increasing the number of hospital beds designated for NICU services at a licensed site.

(j) "Hospital" means a health facility licensed under Part 215 of the Code.

(k) "Initiation of NICU services" means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(l) "Infant" means an individual up to 1 year of age.

(m) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(n) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(o) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

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

(q) " 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.

(r) " 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.

(s) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) parenteral nutrition.

(t) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include bassinets or special newborn care bassinets.

(u) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(v) "Neonate" means an individual up to 28 days of age.

(w) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(x) "Planning area" means the groups of counties shown in Section 12.

(y) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

(z) "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.

(aa) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

(bb) "Replacement of NICU beds" means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(cc) "Replacement zone" means a proposed licensed site which is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.

(dd) "Special newborn care bassinet" means an unlicensed bassinet identified within the hospital obstetrical or newborn service which provides the services identified in subsections (i) through (vi) for infants who require minimal care that goes beyond that of the uncomplicated newborn, or transitional care or developmental maturation in preparation for discharge home. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital.

(i) Care for low birth weight infants between 1,500 and 2,499 grams;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;

(v) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(vi) the administration of oxygen by hood or nasal canula.

(ee) "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.

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

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements for applicants proposing to initiate NICU services

Sec. 4. An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(1) There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(2) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(3) A unit of at least 15 beds will be developed and operated.

(4) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements for applicants proposing to expand NICU services

Sec. 5. (1) An applicant proposing to expand NICU services by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC + 2.06 \sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

Section 7. Requirements for approval for replacement of NICU beds

Sec. 7. (1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the replacement zone.

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

Section 9. Additional requirements for applications included in comparative reviews.

Sec. 9. (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 ~~applicable to comparative reviews~~.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, 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 submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded

Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for

rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(3) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT REWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED~~The minimum number of points will be awarded to an applicant under the individual subsections of this Section for conflicting information presented in this section and related information provided in other sections of the CON application~~.

Section 10. Requirements for approval for all applicants

Sec. 10. 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 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.

(b) Compliance with applicable operating standards.

(c) Compliance with the following applicable quality assurance standards:

(i) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

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

(B) provide NICU services to any individual based on clinical indications of need for the services;

(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.

(ii) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(iii) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(iv) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.

(v) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(vii) An applicant shall develop and implement a system for discharge planning.

(viii) A board certified neonatologist shall serve as the director of neonatal services.

(ix) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.

(x) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(xi) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(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, 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 a separate 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.

(xiii) The applicant shall provide the Department with a notice stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiv) 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 agreed to by the applicant or its authorized agent.

Section 12. Planning areas

Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:

Planning Areas	**Counties**
1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford
8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

Section 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care and Special Newborn Nursery Services/Beds approved by the Commission on ~~March 9, 2004~~SEPTEMBER 18, 2007 and effective on ~~June 4, 2004~~NOVEMBER 13, 2007.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section 5(2).

APPENDIX A

CON REVIEW STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/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

Michigan Department of Community Health (MDCH or Department)
Report to Certificate of Need (CON) Commission
Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards
March 25, 2010

On January 28, 2010, the Michigan Department of Community Health made a recommendation to the CON Commission that it consider these standards for deregulation. The department utilized the Commission's "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review" in evaluating whether the UESWL standards should continue to be regulated. After further deliberation, the Department recommends that this service be deregulated. The Department bases its recommendation on the points listed below. If the Commission chooses to pursue deregulation of UESWL, then the process would be to move to Public Hearing and back to the Commission for final action.

- This is a well established service with Michigan CON standards in place for the past 25 years. It is no longer a new technology. The first approval of a lithotripter device in the United States was in 1984.

- This is a low-cost service. In 2007, Great Lakes Lithotripsy, which has 4 (four) mobile sites in Michigan, provided estimated annual cost data for what both a mobile and fixed unit would cost. Those estimates were that for one fixed site lithotripter unit it would cost $369,996.00 annually whereas a mobile unit serving 10 sites annually would cost $49,239.60 annually per site. The key point is that it is more cost effective to run a mobile route for lithotripsy than it is to have one fixed unit. No significant cost increase has been shown.

- Access does not appear to be an issue, and no access concerns have been brought to our attention through the processes of public hearing or public testimony.

- Currently, Michigan has 9 lithotripters and all of them are mobile units.

- There has been no evidence of proliferation presented. This procedure must be performed in an operating room and under the guidance of an anesthesiologist and is a treatment procedure rather than a diagnostic or exploratory procedure.

- UESWL is a non-invasive medical procedure and patients are most commonly treated as outpatients rather than inpatients.

- Currently, Michigan does not regulate other forms of this procedure such as laser treatments or using lithotripters for biliary procedures. Other states were found to regulate for biliary and not for renal (urinary). This raises the question of whether the intent of the Michigan standards is to regulate the medical procedure rather than the equipment.

- In 2007, the department considered recommending deregulation of the UESWL standards; however, questions were raised by a 2006 Mayo Clinic study[1] that hypothesized a link between UESWL and some chronic health conditions (diabetes mellitus and hypertension). Subsequently, studies in 2008[2] and 2009[3] have refuted the finding of the 2006 study eliminating the department's concern of moving too quickly.

- Some questions/concerns have been raised in regard to the number of re-treatments. Re-treatment data is collected as part of the annual survey process, and currently, the available data does not show increases or unusual numbers of re-treatments.

- Research also shows that expulsive therapy or drug treatment to relax the urinary system muscles to facilitate the passage is a more common treatment than is lithotripsy.

- Only 17 other states regulate Lithotripsy; however, no other states in the mid-west except for Michigan do so. See list below.

CON States w/Lithotripsy Coverage	**CON States w/o Lithotripsy Coverage**	**Non-CON States**
Alaska	Alabama	Arizona
Connecticut	Arkansas	California
Delaware	Florida	Colorado
Dist. Of Columbia	Illinois	Idaho
Georgia	Iowa	Indiana
Hawaii	Louisiana	Kansas
Kentucky*	Maryland	Minnesota
Maine	Mississippi	New Mexico
Massachusetts	Montana	North Dakota
Michigan	Nebraska	Pennsylvania
Missouri	Nevada	South Dakota
New York	New Hampshire	Texas
North Carolina	New Jersey	Utah
South Carolina	Ohio	Wyoming
Tennessee	Oklahoma	**14 States Total**
Vermont	Oregon	
Virginia	Rhode Island	
17 States Total	Washington	
*Coverage for mobile units only.	West Virginia	
	Wisconsin	
	20 States Total	

Source:
American Health Planning Assoc.
2009 National Directory
State Certificate of Need Programs
Health Planning Agencies

[1] Krambeck, A.E., Gettman, M.T., Rohlinger, A.L., Lohse, C.M., Patterson, D.E., & Segura, J.W. (2006). Diabetes mellitus and hypertension associated with shock wave lithotripsy of renal and proximal ureteral stones at 19 years of followup. *The Journal of Urology*, *175*(5): 1742-1747.

[2] Sato, Y., Tanda, H., Kato, S., Ohnishi, S., Nakajima, H., Nanbu, A., et al. (2008). Shock wave lithotripsyfor renal stones is not associated with hypertension and diabetes mellitus. *Urology, 71*(4): 586-591.

[3] Makhlouf, A.A., Thorner, D., Ugarte, R., & Monga, M. (2009). Shock wave lithotripsy not associated with development of diabetes mellitus at 6 years of follow-up. *Urology*, *73*(1): 4-8.

- The following three states are a sample of how other states regulate Lithotripsy under CON:
    - Massachusetts:
        - The website for the Massachusetts Department of Need (DON) lists "that any addition or expansion of, or development of innovative services and new technology, non-acute care services, or freestanding ambulatory surgery centers" are regulated under DON. These new technology services include the use of ESWL for gallstones. Lithotripsy, in general, is regulated under DON but to what extent it is not clear. Additional research found that the MA regulations for Lithotripsy only included the following three categories in which applicants must meet: physical environment requirements, anesthesia requirements, and agreements for inpatient services.

    - Missouri:
        - According to the Missouri Certificate of Need website they regulate Lithotripsy under the major medical equipment acquired over the period of 12 months with an aggregate operating cost of over one million dollars or more. Therefore, they regulate based on a dollar amount threshold. Within the standards, they have a need methodology formula that is applied for lithotripsy when the cost is one million or more in which applicants must then meet to both initiate and expand.

    - New York:
        - According to the New York state laws and regulations contained on their website, they regulate lithotripters for use in renal and biliary (gallstones) procedures. In New York's standards they do list an annual volume capacity for each lithotripter is 600 patients per year which includes both biliary and renal patients.

- On February 22, 2010, MDCH staff met with a Lithotripsy provider to gain input on their thoughts of the current UESWL CON standards in Michigan. Jorgen Madsen from the United Medical Systems presented the Department information regarding their involvement with UESWL being the largest mobile route provider in Michigan.

Public Testimony Regarding Lithotripsy Standards
Presented at Commission Meeting – March 25, 2010
By: Oakwood Healthcare, Inc.

Good Morning,

My name is Monica Harrison, Sr. Planning Analyst at Oakwood Healthcare System.

Oakwood supports continued regulation of this service. We feel the current standards are working well and restrain costs while ensuring access to high quality lithotripsy services. The present standards have allowed the conversion of high cost fixed lithotripters to low-cost mobile services. This in turn has enabled lithotripsy to expand throughout the State and provides a low cost alternative to hospitals that could not otherwise justify the expense of a fixed unit.

Oakwood currently offers mobile lithotripsy at three sites. We feel that it is an important component of quality patient care and a vital service for the communities we serve. Due to the potential for complications, we also believe that it is important that the procedure be performed in the most appropriate setting as stated in the CON standards. The standards help ensure that the highest level of patient safety is met and that the proper equipment and support are utilized in providing this service.

In summary, we would ask that lithotripsy be maintained as a covered CON service.

Thank you for the opportunity to provide these comments.

March 25, 2010

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

Re: CON Standards for UESWL Services

Dear Chairman Goldman,

I apologize for not being able to attend today's CON Commission meeting in person, but appreciate the opportunity to provide input regarding the CON Standards for UESWL (Lithotripsy) Services. It is my understanding that the Michigan Department of Community Health is recommending the deregulation of lithotripsy services from the CON program. This causes me great concern for many reasons, and Sparrow Health System strongly opposes this recommendation.

Sparrow Health System provides lithotripsy services in our surgical suite at Edward W. Sparrow Hospital in Lansing. Lithotripsy uses sound waves to break-up kidney stones so that they can be safely and more easily passed through the bladder and ureter. Although this service is a non-invasive option for treating kidney stones, this should not discount the fact that it is a traumatic procedure to a vital organ. In fact, some studies have shown a complication rate as high as 15% from this procedure, including damage to blood vessels, high blood pressure, chronic impairment of renal function, and even renal failure in the most serious of instances.

The current CON standards for this service help to ensure that facilities performing lithotripsy have the supplies, staff, and facility infrastructure in place to properly handle these complications. For example, Section 3(1) requires facilities to have, amongst other things, the "capability to provide complicated stone disease treatment on-site... On-call availability of an anesthesiologist and a surgeon... Advanced Cardiac Life Support-certified personnel and nursing personnel... IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions." These are requirements of a facility that must be confirmed prior to issuance of a Certificate of Need. Without these CON regulations there is no other State oversight that would ensure these precautionary measures were in place at facilities performing this procedure. Contrary to the Department's claim in their report, there is nothing outside of the CON standards that would require this procedure to be performed in an operating room.

www.sparrow.org

1215 E Michigan
PO Box 30480
Lansing, MI 48909-7980

517.364.1000

The Certificate of Need program is in place to ensure, "the availability and accessibility of quality health services at a reasonable cost and within a reasonable geographic proximity for all people in this state." (MCL 333.22215(2)(a)). The standards for lithotripsy services are the perfect example of CON working at its best. The current standards have encouraged a mobile system for providing this service across the State. These standards have moved this service from 3 fixed units, providing access at only 3 specific sites in the State, to a mobile system that now provides access at more than 70 sites widely dispersed throughout the State, including 4 sites in the U.P. This has allowed access to all patients in the state needing this service, while utilizing a relatively small number of lithotripsy units. The Department notes in their recommendation that "UESWL is a well established and low-cost service." They are correct, but that is only because of the CON regulations in place that have driven this service to a mobile system and created this efficient and effective service.

Sparrow Health System strongly supports the continued regulation of lithotripsy services under the current CON standards. I thank you for your time in considering my perspective and ask for your support.

Respectfully,

Joseph J. Ruth
SVP, Chief Strategy Officer, Interim COO
Sparrow

CC: Dennis A. Swan, President & CEO, Sparrow

March 23, 2010

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

Re: CON Standards for UESWL Services

Dear Chairman Goldman,

Thank you for taking the time to consider my testimony at the January 28th CON Commission meeting regarding the importance of continued regulation of Lithotripsy under the Certificate of Need system. I have attached a copy for those who were not in attendance in January. In anticipation of your continued discussion of this topic at your meeting Thursday, I wanted to provide you with some additional information for your review and consideration prior to the meeting.

You have been charged with the task of deciding if Lithotripsy should continue to be a covered clinical service under CON regulations. The Department has recently provided you with a report detailing their reasons for recommending deregulation of this service. Because it will be impossible to address all of the points made in this report during public comment on Thursday, we thought it was prudent to provide detailed comments today and will be available at the Commission meeting to highlight key points and answer questions.

In deliberating these types of issues, it can often be helpful to look at experiences in other states in trying to predict what might happen in Michigan if lithotripsy is removed from CON regulation. With that in mind, attached please find a summary of Lithotripsy regulation in New Jersey, prepared by local counsel. The attached explains that New Jersey removed lithotripsy from their CON regulations in 1998. The service was still intended to require licensure by the State, but even with that licensure process in place, they still experienced tremendous proliferation of physician owned lithotripters. So much so, that they scrambled in recent years to implement new laws to try to slow down that proliferation through prohibitions on physician ownership.

In addressing the Departments report specifically, let me start by mentioning that the "Guiding Principles" document utilized by the Department in preparing their report was never adopted by the CON Commission and therefore you should not feel compelled to accept the Department's conclusions and recommendations based on these guidelines. However, we do recognize that they certainly serve a useful function, especially in the absence of no other guidelines.

In this report the Department relies on the fact that lithotripsy is a "well established service... no longer a new technology...[and] a low-cost service" to argue that it should be deregulated.

1500 West Park Drive, Suite 390
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682
E-Mail: ums@ums-usa.com

Certainly they are correct that it is well established as the standard of care for treating certain kidney stones. However, the reason it is so well established and low-cost is because of the CON standards in place. The current standards have encouraged the conversion of high-cost, fixed unit lithotripters to low-cost mobile service. This conversion has allowed the service to expand across the State, by providing a low-cost alternative to facilities that otherwise could not justify the expense of a fixed unit. If lithotripsy were to be deregulated and urologists and hospitals started buying their own equipment, this would have a negative impact on the availability and cost of operating a mobile route. The mobile business would be diluted, and as a consequence, the price for providing mobile service in the more rural and smaller community hospitals would increase, potentially to the point where it financially would no longer make sense for them to provide the service, and therefore restricting access.

The Department recognizes that access is not a problem currently. We believe that deregulation would, in fact, negatively impact access in the long-run. New Jersey hospitals found it difficult to compete as providers of lithotripsy services outside of CON regulations because the physicians who were performing the procedure in the hospital operating rooms under CON were moving those procedures to their offices. Aside from the safety concerns associated with this move, it made it uneconomical for the hospital to maintain the service and therefore restricted access for lower-volume urologists who were utilizing the equipment in the hospital ORs but could not justify purchasing their own equipment.

In regards to the safety concerns, the Department makes the statement in their report that, "This procedure must be performed in an operating room and under the guidance of an anesthesiologist." Although it is true that this is arguably the most appropriate setting for a lithotripsy procedure, unfortunately outside of CON there is nothing prohibiting a urologist from performing this procedure in their offices. This is exactly why the CON regulations should remain in place. New Jersey experienced a proliferation of physician-owned lithotripters. Many of these physicians also opened their own outpatient surgery centers and did continue to provide the procedure in licensed operating rooms. However, for those without ASCs the physician office is being used. New Jersey still requires licensure of lithotripsy services and therefore still monitors the conditions under which the procedure is performed. However, in Michigan the only regulation of lithotripsy outside of CON is Radiation Safety where the state only ensures that the room where lithotripsy procedures will be performed has appropriate lead shielding in place to contain radiation within the procedure room. These regulations would not, by any means, ensure appropriate staff, supplies, or support services would be available to patients undergoing the lithotripsy procedure. Although lithotripsy is a non-invasive procedure usually treated in an outpatient setting, it is still a serious procedure that requires monitoring of the patient for internal complications after the procedure is finished.

The Department acknowledges that "it is more cost effective to run a mobile route for lithotripsy than it is to have one fixed unit." However, the Department uses this information to conclude that lithotripsy would continue to be provided via mobile routes, even if CON regulations are no longer in place to encourage that. What the Department fails to recognize is that currently the reason why urologists do not own their own lithotripters is not because it is more cost effective to lease time on a mobile route, but rather because CON regulations discourage fixed units and

make it extremely difficult, if not impossible to obtain CON approval for them, especially for an individual physician. Without CON regulations in place, why would a physician not purchase his/her own lithotripter rather than lease one from a mobile route? With the purchase of a fixed unit they would have a depreciable asset and not have to continuously pay a mobile service provider. Certainly, under the current CON regulations, the mobile service is more cost effective for the State as a whole, as it balances sharing fixed costs over a larger number of host site facilities with expanded access, allowing for facilities with lower lithotripsy volume to still be able to afford to provide the service. However, outside of this system, as high-volume urologists determine it to be financially more advantageous for them to own their own litho unit, and that volume comes out of the mobile route, those fixed costs will have be spread over a smaller number of host sites, increasing their costs and likely, eventually leading to the reduction in the number of mobile units in the State. Great Lakes Lithotripsy is currently planning an expansion to one of our mobile lithotripsy routes later this year. However, we are only able to make that financial commitment because of the current CON standards which provide for a predictable business environment.

The Department also claims that, "There has been no evidence of proliferation presented." We hope you will agree that the attached description of the proliferation in New Jersey upon removing lithotripsy from CON regulations is sufficient proof that proliferation is likely. It is important to note that New Jersey experienced this proliferation despite still requiring licensure of the service. It is also important to understand that lithotripsy is not covered by Stark regulations, a federal regulation that will, at times, help to limit proliferation of physician-owned equipment and services where self-referral is involved. Removing lithotripsy from CON will introduce a profit motive that does not currently exist. There are other options for treating kidney stones and it is possible that profit motives could encourage the choosing of lithotripsy over other alternative treatments rather than solely based on the most effective treatment for each patient's situation.

Noted in the Department's report is the fact that they have been collecting data on re-treatments (potentially an indicator of mis-use if re-treatment levels get too high) in the annual survey and have seen no increases or unusual numbers of re-treatments. Although the Department uses this to justify deregulations, it seems that this demonstrates another reason for continued regulation. Without CON regulation the State has no authority to collect data on lithotripsy volumes or re-treatment rates. Collecting this data allows the Department the ability to act in the case that abuse becomes apparent. In addition, because the annual survey data has historically been relatively incomplete, with last year being the first year that nearly 100% of facilities reported, it would be prudent for the Department to reserve judgment as to conclusions based on retreatment data in Michigan until we have several years of complete data to review.

In looking at the Guiding Principles document provided by the Department we noted that lithotripsy only met 3 of the 9 principles that would indicate deregulation. Of those 3 principles, many, if not most, of the CON Covered Clinical Services meet those indications for deregulation, namely that they have capital costs below the current covered capital expenditure threshold ($2,942,500), low operating costs, and have become an accepted standard of care provided in the community setting. In regards to the other principles, the capital and operating costs have

not decreased significantly over the past 3 years; as mentioned already, the only other organization monitoring the provision of lithotripsy in Michigan is Radiation Safety, which does not regulate the provision of care; the current standards do establish a methodology that quantifies how the need for lithotripsy service shall be demonstrated; even the Department clearly states in their report that the CON requirements have not negatively impacted geographic access, but rather have enhanced access; and reimbursement policies and other quality assurance mechanisms are not in place to limit unnecessary or inappropriate utilization of lithotripsy. In fact, the opposite is true as each time a lithotripsy procedure is performed the urologist is compensated and a facility fee is paid and there are no anti-self-referral regulations in place that regulate lithotripsy.

In January I, and many others, pointed out many positive aspects to the current CON Review Standards for Lithotripsy Services. They ensure that patients are treated in the most appropriate setting, with all of the infrastructure in place to deal with any emergencies and complications that may arise from this treatment. They also have served this State well in creating, as the Department staff put it, "a well established and low cost service." We are certainly open to suggestions for improving the current system and would even be willing to make suggestions if the Commission so desires. However, we feel it is critical to maintain CON regulation of lithotripsy to prevent the proliferation seen in New Jersey and other states and to save Michigan the cost and aggravation of scrambling to re-regulate a service that didn't have to be deregulated in the first place. I thank you for your time in reviewing these materials and ask for your support.

Respectfully,

Jorgen Madsen
CEO

WILENTZ GOLDMAN &SPITZER P.A.

ATTORNEYS AT LAW

90 Woodbridge Center Drive
Suite 900 Box 10
Woodbridge, NJ 07095-0958
732.636.8000
Fax 732.855.6117

Meridian Center I
Two Industrial Way West
Eatontown, NJ 07724-2265
732.542.4500
Fax 732.493.8387

110 William Street
26th Floor
New York, NY 10038-3901
212.267.3091
Fax 212.267.3828

Two Penn Center Plaza
Suite 910
Philadelphia, PA 19102
215.940.4000
Fax 215.636.3999

Park Building
355 Fifth Avenue
Suite 4000
Pittsburgh, PA 15219
215.940.4000
Fax 215.636.3999

website: www.wilentz.com

Direct Dial: (732) 855-6047
Direct Fax: (732) 726-6552
E-mail: mschaff@wilentz.com

DAVID T. WILENTZ (1919-1996)
G. GEORGE GOLDMAN (1922-1950)
HENRY M. SPITZER (1928-1988)

WARREN W. WILENTZ
MORRIS BROWN
FREDERIC K. BECKER[2]
NICHOLAS L. SANTOWASSO
RICHARD F. LERT[2]
JOHN A. HOFFMAN
STEPHEN E. BARCAN
FRANCIS V. BONELLO
BARRY M. EPSTEIN[2,10]
VINCENT P. MALTESE
DAVID M. WILDSTEIN
GORDON J. GOLUM
MARVIN J. BRAUTH[2]
STUART A. HOBERMAN[2,3]
STEPHEN A. SPITZER
ANNE S. BABINEAU[2]
CHRISTINE D. PETRUZZELLI
BRIAN J. MOLLOY
RANDALL J. RICHARDS
JOSEPH J. JANKOWSKI
DAVID S. GORDON
FREDERICK J. DENNEHY
ROY H. TANZMAN[2]
STEVEN J. TRIPP
JAY J. ZIDNIEWSKI
ALAN WASSERMAN[<]
JAMES E. TRABILSY
MAUREEN S. BINETTI[<]
ANTHONY J. PANNELLA, JR.
MICHAEL J. BARRETT[<]
MICHAEL F. SCHAFF[2,7]
ANGELO JOHN CIFALDI
KEVIN M. BERRY[2]
JOHN T. KELLY[2]
C. KENNETH SHANK[2]
EDWIN LEAVITT-GRUBERGER[2]
BRUCE M. KLEINMAN[2,5]
BARRY A. COOKE[2]
JON G. KUPILIK
PETER R. HERMAN[2]
EDWARD T. KOLE

HESSER G. McBRIDE, JR.
ERIC JOHN MARCY
ROBERT C. KAUTZ[2,8]
VIOLA S. LORDI[2]
LYNNE M. KIZIS
KEVIN P. RODDY[2,6,9]
DANIEL S. BERNHEIM 3d[1,3]
DAVID H. STEIN
DOUGLAS WATSON LUBIC[2]
DOMINICK J. BRATTI
LISA A. GORAB[2]
LAWRENCE F. JACOBS[2]
BETH HINSDALE-PILLER
FRED HOPKE[1]
DONALD E. TAYLOR[2]
BARRY R. SUGARMAN[2]
BRETT R. HARRIS[2,3]
JEFFREY W. CAPPOLA
ALFRED M. ANTHONY[2]
DARREN M. GELBER[2,10]
MATTHEW M. WEISSMAN[2]
WILLIAM J. LINTON
DONNA M. JENNINGS
GIOVANNI ANZALONE
PETER A. GREENBAUM[2]
WILLARD C. SHIH[2]
BLAIR R. ZWILLMAN[2,10]
LAWRENCE C. WEINER[2]
LAURIE E. MEYERS[2,4]
JOHN M. CANTALUPO[2]
BARBARA G. QUACKENBOS[2]
DAVID P. PEPE
JOHN E. HOGAN[2]

OF COUNSEL
ROBERT A. PETITO
HAROLD G. SMITH
ALAN B. HANDLER[8]
MYRON ROSNER[2]
R. BENJAMIN COHEN

COUNSEL
RUTH D. MARCUS[1,3]
RICHARD J. BYRNES
JAMES P. LUNDY[2,3]
JAMES E. TONREY, JR.[2]

DEIRDRE WOULFE PACHECO[2]
ROBERTO BENITES
JONATHAN J. BART[1,2,3]
YVONNE MARCUSE
ABBY RESNICK-PARIGIAN[2,3]
BRIAN KALVER[2]
ELLEN TORREGROSSA-O'CONNOR
AMANDA F. SHECHTER[2]
BARBARA J. KOONZ[2]
TODD E. LEHDER[2,7]
PHILIP A. TORTORETI[11,12]

ASSOCIATES
LINDA LASHBROOK
LORETTA KIRSCH PRIVES[2]
ELIZABETH C. DELL[2]
KELLY A. ERHARDT-WOJIE[5]
FRANCINE E. TAJFEL[2]
ALBERTINA WEBB[2]
JOHN P. MURDOCH II
MARY H. SMITH
EDWARD J. ALBOWICZ[2]
ANNA I. MONFORTH
STEPHANIE D. GIRONDA
EVERBITT M. JOHNSON[2]
ALEX LYUBARSKY[2]
KEVEN H. FRIEDMAN[2,9]
GREGORY D. SHAPPER[2,<]
JESSICA S. PYATT
LOUIS J. SEMINSKI, JR.
DANIEL R. LAPINSKI[2]
MICHAEL F. FRIED[2]
MICHELE C. LEFKOWITZ[2]
DASHIKA R. WELLINGTON[2]
ROBERT L. SELVERS[2]
PAMELA R. GOLD-ZAFRA[2]
ALYSON M. LEONE[2]
VINCENT CHENG[2]
MICHAEL J. WEISSLITZ
JONATHAN M. BUSCH[2]
JAMIE M. BENNETT[2]
MARCELLO DE PERALTA[1,2]
KEITH L. HOVEY[2]

JOSEPH C. RUSSELL JR.[3]
JON S. POLEVOY
EMILY D. VAIL[3,4]
CHERYL E. CONNORS
CHAD B. SIMON[2]
ANTHONY WILKINSON[2]
DENIZA G. GERTSBERG[2]
JAY B. FELDMAN[2]
LOUIS A. GREENFIELD[2]
JULIA A. LOPEZ[2]
AMY HERBOLD
ERIC L. BUEDE[2]
DARRON E. BERQUIST[1,2]
DOUGLAS M. SILVESTRO
DANIEL J. KLUSKA
KARIN K. SAGE
MICHAEL L. GALVIN
SATISH V. POONDI
ERICA A. RODRIGUEZ
CARRIE S. FORD
RACHEL M. COLANCECCO[2]
VICTORIA HWANG-MURPHY
GLENN P. PRIVES
ANNEMARIE C. TERZANO[2]

< Certified Civil Trial Attorney
□ Certified Criminal Trial Attorney
‡ Certified Matrimonial Attorney
† Certified Workers Compensation Attorney
* National Certified Civil Trial Specialist Approved by the ABA
1 Not admitted NJ
2 Admitted NY
3 Admitted PA
4 Admitted CT
5 Admitted DC
6 Admitted MA
7 Admitted MD
8 Admitted VA
9 Admitted CA
10 Admitted FL
11 Admitted PR
12 Admitted VI

February 19, 2010

VIA E-MAIL (jmadsen@ums-usa.com)
Jorgen Madsen, President
United Medical Systems (DE), Inc.

Re: History of Lithotripsy Regulation in New Jersey

Dear Jorgen:

Pursuant to your request, I am writing to provide you with a brief summary of the history of the regulation of extracorporeal shockwave lithotripsy (hereinafter referred to as "lithotripsy") in New Jersey. In 1998, lithotripsy became exempt from the certificate of need ("CON") requirement by an act of the legislature. (See New Jersey Statute P.L. 1998, c.43, 10). As described below, this initial move toward the deregulation of lithotripsy services in New Jersey, combined with the advent of transportable lithotripsy services, made it difficult for New Jersey hospitals to compete as providers of lithotripsy services, which, in turn, has made it difficult for hospitals to plan for the provision of services to meet the needs of their communities. This led New Jersey's legislature to add a new layer of regulation to lithotripsy in 2009 by imposing a prohibition against physician ownership of lithotripsy facilities to which they refer patients. (See New Jersey Statute P.L. 2009, c.24).

The lifting of the CON requirements for lithotripsy services in 1998 was part of a larger retraction of New Jersey's CON program that included the elimination of the CON requirement for a large number of other health care services, including magnetic resonance imaging and ambulatory

surgical services. Since this statutory change, the New Jersey Department of Health and Senior Services (the "NJDHSS") has taken the position that the services that no longer require a CON are still subject to regulation by the NJDHSS. The NJDHSS maintains that the operators of all such services are required to apply for and obtain operating licenses from the NJDHSS before providing any services, must continuously maintain those licenses, and must comply at all times with the NJDHSS regulations applicable to health care facilities, in general, and to the specific service. This position was not necessarily obvious from the language in the CON and licensure statutes and earlier NJDHSS regulations, which have never been well-coordinated, and confusion ensued for a few years during which some physicians and other health care firms proceeded to establish and operate services that no longer required a CON without obtaining a license to operate the service, and without complying with the NJDHSS's regulatory standards. After years of regulatory action and further legislation, the regulatory regime for these de-certificated services has been cleared up for the most part (but not, in our view, entirely).

When the CON requirement for lithotripsy services was eliminated in 1998, the NJDHSS obviously lost its control over the proliferation of lithotripsy services in New Jersey. The confusion over the regulatory regime applicable to lithotripsy also challenged the NJDHSS's control over the quality and safety of lithotripsy. However, there was no immediate proliferation of lithotripsy services in New Jersey because the fairly small community of providers and potential providers of lithotripsy services at that time were aware that the NJDHSS took the position that a lithotripsy service had to be licensed by the NJDHSS in order to operate, and there was, in effect, a moratorium on the establishment of new mobile and transportable lithotripsy services as the NJDHSS was developing new regulatory standards for these services. The current NJDHSS lithotripsy regulations address a range of public policies related to lithotripsy services, including the construction and design of the facility (whether the lithotripter is fixed, mobile or transportable), the inspection and maintenance of the equipment, the qualifications and oversight of the staff, and access to lithotripsy services for those without the means to pay.

A key element of New Jersey's health care regulatory scheme is a statutory prohibition against physician self-referrals that dates back to 1991 (the "Codey Law") (see New Jersey Statute P.L. 1991, c.187), which was two years after the enactment of the initial federal prohibition against self-referrals for clinical laboratory services (the "Stark Law"), and two years before the Stark Law was expanded to include other designated health services. (See 42 USC § 1395nn). As later confirmed by the federal courts, the expanded Stark Law did not apply to lithotripsy services. (See *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002). Similarly, the Codey Law, as initially enacted, did not apply to lithotripsy services.

In 2009, the New Jersey Legislature added greater regulation of outpatient healthcare services when new legislation was enacted that, among other things, eliminated the exception for lithotripsy under the Codey Law as it applies to new investments in lithotripsy services. (See New Jersey Statute P.L. 2009, c.24). This new legislation prohibits physicians from having a financial interest in a

WILENTZ
GOLDMAN
&SPITZER P.A.
ATTORNEYS AT LAW

lithotripsy service to which they refer patients, unless the financial interest already exists on the effective date of the legislation (at the end of March 2010). This additional layer of regulation on lithotripsy was, we believe, an attempt to address the disadvantages that hospitals have in competing with urologists in providing lithotripsy services, and the difficulty hospitals may have in planning for the provision of services to meet their community needs for lithotripsy services, when urologists have a fairly unfettered route to setting up their own transportable lithotripsy services.

We do not have any data on the transfer of profits from lithotripsy services from hospitals to physicians that occurred in the years following the de-certification of lithotripsy in 1998, but we would imagine that it was substantial and that many hospitals would have had trouble just recouping the costs on their lithotripsy programs, while the physician-owners of lithotripsy equipment reaped substantial profits. Whether urologists and hospitals are on a level playing field with regard to competing for lithotripsy business is a complicated question, and the answer depends on one's perspective. But, in the view of New Jersey's policymakers and legislature, lifting governmental control over the establishment of new lithotripsy services resulted in an undesirable situation that New Jersey is now trying to right through its self-referral law.

We hope that this summary has been helpful to you. Please feel free to contact either me or Brian Kalver, Esq. of this office with any questions you may have. As I believe I mentioned, I will be out of the office next Tuesday through Friday, in Miami, where I will be speaking at a Physician Law Institute conference.

Very truly yours,

MICHAEL F. SCHAFF

#3258956 (154315.001)

Testimony Re: UESWL Services
CON Commission Meeting
January 28, 2010

Good morning/afternoon. I am Jorgen Madsen, the CEO of United Medical Systems, minority owner of Great Lakes Lithotripsy which owns and manages 4 mobile lithotripsy routes in Michigan. Thank you for this opportunity to provide comments regarding the CON Standards for Lithotripsy Services.

Great Lakes Lithotripsy strongly supports the current CON standards for this service and believes they are working well to ensure access to high quality lithotripsy services while restraining costs. We strongly oppose the Department's recommendation to deregulate this service for many reasons.

These standards may be the perfect example of CON at its finest. The current standards have moved Lithotripsy from a very expensive, fixed unit system, to a low-cost mobile system. By encouraging fixed units to be converted to mobile, these standards have increased access exponentially while keeping costs low. In fact, in 1998 there were 5 fixed lithotripsy sites and 9 mobile lithotripsy host sites, providing access at only 14 sites total across the entire state. 12 years later there are now 9 mobile lithotripsy routes with 11 lithotripsy units total, providing service to 70 host sites in the State; 5 times as many access points than under the previous system but with only twice as many lithotripsy units. Because lithotripsy is a relatively low volume procedure at any single facility, this system has created efficiencies by allowing multiple facilities to utilize the same equipment.

The CON standards provide assurance that facilities providing this service have the necessary equipment and support services to ensure patient safety. These provisions have prevented proliferation of lithotripsy units into physician offices where those necessary support services do not exist. Although lithotripsy is a non-invasive procedure, it is traumatic for the kidney and the patient must be followed carefully to ensure there is no renal bleeding or developing hematomas, which are known complications of the procedure. It is important that these patients are treated in an appropriate facility. It is also vitally important that the physician performing the procedure be properly trained and credentialed, all requirements of the current CON standards.

Patient demand is being met under the current system in a very timely and efficient manner. The current rules allow for the addition of lithotripsy units when demand exceeds capacity, providing for a reasonable expansion of services. Some have recently argued that the expansion criteria are too restrictive and that it is impossible to meet the volume qualifications. We would disagree. In fact, we have qualified under the current rules for expansion of 2 of our 4 routes already, and will be qualifying to expand a third route sometime this year. The rules are reasonable and fair.

The CON staff are recommending deregulation under the assumption that it will not result in proliferation of services, but have provided no support for this assumption. In years past, this Commission has been approached by physicians wishing to provide this service in their offices with their own lithotripsy units. Why would we assume that they would not proceed with their plans once the CON system is no longer in place to ensure this procedure is performed in the most appropriate setting?

In closing, we strongly encourage the continued regulation of lithotripsy services under the current CON standards. The current rules are effective in upholding the 3 tenants of CON – Cost, Quality, and Access. As pointed out by Department staff in their recommendation, there were no public comments advocating for deregulation of this service. Why change something that works so well? I am happy to answer any questions you may have.

ALLIANCE FOR HEALTH
POSITION PAPER
on
Behavioral Beds

March 25, 2010

Subject: The State's Special Population Bed Pool for Behavioral Beds.

1. PURPOSE: This position paper has been prepared in order to attempt to change and redirect the State's current 400 special needs population behavioral bed pool for use by documented patients with Alzheimer's disease and related dementia. Specifically, it is recommended that the 400-bed pool for "behavioral patients" be eliminated in favor of an increased pool of beds designated for Alzheimer's patients.

2. POINTS SUPPORTING RECOMMENDED POSITION: A redirection of use of the current behavioral beds for sole use for Alzheimer's care is desired based upon the following:

a. The current Alzheimer's bed pool has been exhausted.

b. The rapid growth rate of Alzheimer's disease dictates that additional special needs beds be allocated for Alzheimer's care in licensed nursing home long term care facilities.

c. Michigan has inadequately allocated sufficient resources to meet the growing demand for Alzheimer's care within the State.

d. The standards of care for Alzheimer's patients are uniquely different than those of the customary aged geriatric patient residing in long term care facilities. These two populations have great difficulty cohabitating and require different physical environments.

e. Alzheimer's is a terminal organic brain disorder or disease and not an ongoing mental illness.

f. As the Alzheimer's disease progresses through its set stages toward death, patients will certainly suffer periods of behavioral challenge. These instances are being addressed with great success through proper medication, activity programming, staff training and on site physician oversight / supervision.

3. POINTS CHALLENGING THE CURRENT POSITION: The current allocation of 400 Medicaid-supported Special Population beds for "Behavioral Patients" is believed ill advised and inappropriate public policy based upon the following:

a. The current definition of a "behavioral patient" found in Section 1(4) (a) of the Nursing Home – Special Populations Addendum states that "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.

b. The state's Mental Health Code includes in the definition of individuals who can be involuntarily admitted to acute inpatient psychiatric facilities an individual"*whose judgment is so impaired that he or she is unable to understand his or her need for treatment and whose continued behavior as the result of this mental illness can reasonably be expected, on the basis of competent clinical opinion, to result in significant physical harm to himself or herself or others.*" In part, the language in the CON standards mirrors this. It would appear that such patients would require acute psychiatric care, not a long term care facility.

c. The definition of behavioral patient defines an individual whose current behavior would best be treated and stabilized through the temporary placement in an acute care hospital psychiatric unit. Direct placement of an individual presenting these behaviors into a long term care "behavioral bed" unit without following the State's Mental Health Code would be highly dangerous and contrary to generally accepted medical practice. This definition fails to set demographic parameters such as the age of the patient.

d. Designating 400 beds for the long term housing of patients presenting behavioral challenges as currently defined appears contrary to the long-standing direction adopted by the MDCH to not provide "institutions" for individuals suffering from a mental illness treatable with psychoactive medications. If creating and activating these beds for behavioral patients is the new direction the State wishes to pursue, why is the State now attempting to close the Birchwood long term care psychiatric nursing home in Traverse City? Would awarding all 400 beds to a single provider make better sense than awarding 10 to 20 bed parcels to multiple individual providers? Would doing so create a new statewide sponsored mental health institution?

e. Years of experience have taught the Michigan long term care provider that admitting patients with a history of difficult behavioral challenges forces the facility to either not admit them all; to isolate them if they are in the facility; or to attempt to seek assistance for mental health services. The appropriate option would be to admit them and to get them the services that they require. Once they receive treatment and stabilization in an acute care setting, their return placement in a long term care setting is both appropriate and supportable. It appears that many long term care facilities may be unaware of how to gain mental health services for their patients whose behavior is both inappropriate and dangerous. It would be a travesty if behavioral patients are warehoused without treatment. If this occurs, facilities with behavioral patients and their leaders will remain accountable to State and Federal regulators for the safety and health care treatment of potentially untreated and dangerous residents.

f. It is also believed that any facility wishing to use behavioral beds to provide Alzheimer's care is simply using a ploy to avoid Alzheimer care programming requirements found in State law. This should be corrected by increasing the special pool of beds allocated for Alzheimer's patients, not the continuation of a pool of beds for behavioral patients.

Michigan Department of Community Health (MDCH or Department) Report to Certificate of Need (CON) Commission
Portable Computed Tomography (CT) Scanner Update
March 25, 2010

The Department is providing an update on the pilot program for allowance of hospital-based portable CT scanners contained in the CT Scanner Services standards. Section 13 of the standards contains the requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition. All applicants to be approved for a hospital-based portable CT scanner had to have their applications submitted to the Department by October 1, 2008. Therefore, this pilot program is no longer in effect for new applicants.

Section 19(5) of the CT standards contains project delivery requirements for those applicants who applied, and were approved, for the hospital-based portable CT scanner under Section 13. Those project delivery requirements include quarterly reporting on utilization, cost, and benefit for patient care as compared to the use of the full-body CT scanners. The Department was to summarize this information and provide an assessment to the Commission. This report reflects the summary and assessment by MDCH.

There were four applicants who applied to initiate a portable CT scanner:

1. University of Michigan – Approved on 10/31/08 and began operation on 2/2/09.
2. St. John – Approved on 1/23/09 – Withdrawn and will not be initiating.
3. Spectrum – Approved on 2/20/09.
4. Bronson – Approved on 2/27/09.

All applicants were approved by the Department to initiate. To date, one applicant (St. John) has withdrawn and will not be initiating a portable CT scanner. The University of Michigan which began operation of its portable CT scanner in February of 2009 has provided an update to the Department, and that is attached to this report. It includes utilization figures by month as well as cost and benefit information. The other two CON holders, Spectrum and Bronson, are expected to report the status of their respective CTs to the Department. The deadline for their reporting was February 28, 2010. As of March 16, the Department is still waiting for information from the two programs regarding the dates their portable CT scanners became operational.

<u>MDCH Assessment:</u>

It is difficult to fully assess the potential impact of portable CTs versus large fixed units based upon such a small statewide sample. There are only three in operation, and all of them are located in small, central and urban geographic areas of the state.

The data and information provided by the University of Michigan which has had its portable CT scanner in operation for one year is thorough and helpful. However, it is questionable whether the Commission will be able to translate the experience of one facility to statewide policy.

A concern that all hospitals would apply for a portable hospital-based CT scanner is not supported. Although the application window period was brief, the state's hospitals are extremely familiar with the CON process. If they were waiting for the changes in the standards to permit portable units, they could have easily submitted a Letter of Intent and/or application. Concerns of statewide proliferation are not supported.

If the Commission continues to be concerned that these types of units have the potential to proliferate, and increase health care costs, it is suggested that the standards be modified to include a second window period of 18 months. It will then be possible to more accurately gauge statewide hospital interest in these units and to collect a greater amount of data to evaluate during the next review cycle in 2013.

University of Michigan Health System – Portable CT Utilization Experience

Over the past 11-months the University of Michigan Health System (UMHS) has had a positive experience utilizing its Portable CT Scanner. Patients who were formerly unable to receive a head CT because they were too unstable to leave the Neurosurgery Intensive Care Unit (NICU) can now be diagnosed at the bedside. This is not a high quantity; however, when a patient is very sick or critically ill, having the capability to perform bedside evaluation is invaluable. The information that the portable scan provides enables NICU staff to take immediate action at the bedside or get the patient quickly to the Operating Room. This has been the case with several patients since UMHS started the portable scanning process.

Patient safety has greatly improved as NICU staff no longer need to put the patient at risk for losing important catheters and lines. These patients often have the following: foley catheter, peripheral IV's, a central line, an arterial line, an endotracheal tube, and a ventriculostomy. If these patients are taken to the fixed scanner, they must be transferred from their bed to a gurney, transported through hallways, down elevators and to the location, transferred off of the gurney onto the scanner table, scanned, taken back to the gurney, reverse the trip and then be hoisted back into bed. There have been situations where patients required a catheter or line replacement due to accidental discontinuation resulting from these trips. Each procedure that the patient has to endure because of accidental discontinuation puts them at more risk of adverse events. Since initiating Portable CT scanning, staff estimates that the rate of accidental device lose have been reduced 30-50%.

Staff are now able to provide a quicker diagnostic capability at the bedside. When a patient has an emergent decline, a portable scan is ordered. The nurse prepares the patient within the room per a protocol developed jointly by radiology techs and bedside NICU nurses. By the time the patient is ready to be scanned, the scanner is typically at the bedside and the process occurs. Some of the earlier statistics surrounding times illustrate equal or longer times with the portable scans; however, it is the distinct impression of the NICU nurses and physicians that the bedside procedure is timelier. It is definitely less of a staff work burden preparing the patient within the room versus getting them to a gurney and ready for transport as described above.

As the data below indicates, there has also been substantial cost-savings associated with reduced patient transport needs which involve SWAT and nursing.

Portable CT Studies Performed at University of Michigan Hospital
Period: February, 2009 - December, 2009

Month	Volume
February, 2009	69
March, 2009	67
April, 2009	46
May, 2009	47
June, 2009	51
July, 2009	69
August, 2009	82
September, 2009	88
October, 2009	42
November, 2009	44
December, 2009	54
Total for 11 Months	659

Projected Cost Savings:

Hourly Expense for SWAT Team Member including fringe benefits: $52.20/hr. or $.87/minute
Average Time (includes travel time to and from ICU, CT set up and study) for CT Study requiring one SWAT member: 80 minutes

Dollars saved for one SWAT member by using Portable CT at the bedside = 80 minutes * 659 studies * $.87/minute = $45,866

Note: More than one SWAT Team member can accompany a patient transported from Neuro ICU

Source: University of Michigan Health System Departments of Neurosurgery and Radiology, 2010

DEPARTMENT OF COMMUNITY HEALTH

~~LEGISLATIVE AND POLICY~~ **HEALTH POLICY AND REGULATION ADMINISTRATION**

CERTIFICATE OF NEED

These rules become effective immediately upon filing with the Secretary of State unless adopted under sections 33, 44, or 45a(6) of 1969 PA 306. Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the department of public health by sections 2226, 2233, ~~22106, 22123,~~and ~~22135~~22255 of **1978 PA 368, MCL 333.2226, MCL 333.2233, and MCL 333.22255, and Executive Regorganization Order No. 1996-1, MCL 330.101.** ~~Act No. 368 of the Public Acts of 1978, as amended, and section 9 of Act No. 380 of the Public Acts of 1965, as amended, being 167; 333.2226, 333.2233, 333.22106, 333.22123, 333.22135 333.22255, and 16.109 of the Michigan Compiled Laws~~).

R 325.9101, R 325.9103, R 325.9105, R 325.9109, R 325.9121, R 325.9125, R 325.9201, R 325.9204, R 325.9205, R 325.9206, R 325.9207, R 325.9208, R 325.9215, R 325.9227, R 325.9229, R 325.9301, R 325.9303, R 325.9401, R 325.9403, R 325.9413, R 325.9415, R 325.9417, R 325.9419, R 325.9501, R 325.9503, and R 325.9517 of the Administrative Code are amended; R 325.9501 R 325.9503, R 325.9509, R 325.9517, and R 325.9525 are rescinded from the Administrative Code, and R 325.9210, R 325.9228, R 325.9504, R325.9526, R 325.9551, R 325.9552, R 325.9553, R 325.9554 and R 325.9555 are added to the Administrative Code as follows:

PART 1. GENERAL PROVISIONS

R 325.9101 Definitions; A to **D**~~E~~.

Rule 101. As used in these rules:

(a) "Applicant" means the person**, as defined in section 1106 of the code, or a governmental entity, as defined in section 1104 of the code,** applying for a certificate of need **and authorized to conduct business in the State of Michigan.**

(b) "Application" means the ~~forms provided by the~~ department **forms, in electronic or in paper format,** that are currently in effect **at time the application is submitted,** and any information or documentation prespecified in the forms to be provided as attachments or supplements. ~~The application provided by the department shall be developed after consultation with representatives of regional certificate of need review agencies and facilities and agencies subject to certificates of need.~~

(c) "Appropriate regional certificate of need review agency" means the regional certificate of need review agency ~~designated by~~ **that** the department **designates** ~~pursuant to~~ **under** section 22226 of the code **that is** within ~~whose~~ **the** geographical review area **where an applicant proposes to locate** a project ~~is proposed to be located~~.

(d) "Bureau" means the administrative unit of the department **that the director designates** ~~designated by the director~~ as responsible for the certificate of need program.

(e) "Code" means **1978 PA 368, MCL 333.1101.**~~Act No. 368 of the Public Acts of 1978, as amended, being §333.1101 et seq.~~ of the Michigan Compiled Laws.

(f) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area ~~and which~~ **that** are being reviewed comparatively ~~in~~ accord**ing** ~~ance~~ **to** ~~with~~ these rules.

(g) "Completed application," except as provided in R 325.9229, means the application submitted by the applicant, including any additional information provided by the applicant on or before the date the application is deemed complete ~~pursuant to~~ **under** R 325.9201(3). ~~An applicant may request, and the department may allow, the submission of information after the date the application is deemed complete if the application is not subject to comparative review and if the applicant authorizes an extension to the date a decision must be issued.~~

(h) "Completed project" means a project ~~for which~~ **that** the department has determined both of the following:

(i) That all activities and construction necessary to offer the services, beds, facilities, or equipment approved by a certificate of need have been executed in compliance with the terms and conditions of the certificate of need.

(ii) That the project has been implemented as defined in R 325.9103(b).

~~(i) "Force account" means an account established by a formal action of the governing board of a health care facility to commit its own funds for a construction project undertaken by the health care facility where the construction is managed and supervised by the health care facility acting through its own employees or officers and where the construction is performed by employees of the health care facility and not by contractors or subcontractors.~~

(i) "Department" means the michigan department of community health.

(j)"Director" means the director of the michigan department of community health.

R 325.9103 Definitions; I to L.

Rule 103. As used in these rules:

(a) "Incur an obligation" means entering into either of the following:

(i) An ~~enforceable~~ **executed** contract or contracts ~~or force account~~ for the construction**, acquisition, lease, or financing** of~~, or enforceable contract or contracts for the acquisition, lease, or financing of,~~ all or substantially all**,** of the project, as determined by the department.

(ii) An ~~enforceable~~ **executed** contract or contracts ~~or force account~~ for the construction**, acquisition, lease, or finance** of~~, or an enforceable contract for the acquisition, lease, or financing of,~~ a phased project. A phased project is a project accomplished in segments over a period of time in compliance with a project timetable acceptable to the department and approved in the certificate of need.

(b) "Implement," except as provided in R 325.9403~~(4)~~,**(5)** means **one** ~~1~~ of the following~~, as applicable~~:

(i) For a project that involves any of the following, the performance of the first surgical procedure **listed below** ~~or the treatment of the first partial hostalization [sic] psychiatric patient, as applicable~~:

(A) Extrarenal **(heart/lung and liver)** transplantation.

(B) Open heart surgery.

~~(C) Partial hospitalization psychiatric program services.~~

(ii) For a project that involves any of the following, **the performance of the first procedure or** the signing of a~~n enforceable~~ contract ~~for the acquisition of the equipment~~ **that**

specifies the installation date of the equipment must occur within 24 months and the first procedure within 30 months of the effective date of the certificate of need:

(A) **Urinary** ~~E~~**e**xtracorporeal shock wave lithotripsy **(UESWL)**.

(B) Megavoltage radiation therapy **(MRT)**.

(C) Positron emission tomography (PET) scanning.

(D) Computed tomography (CT) scanning.

(E) Cardiac catheterization.

(F) Magnetic resonance imaging (MRI).

(G) Air ambulance services.

~~The enforceable contract shall specify that the installation date of the equipment shall be within 24 months after the effective date of the certificate of need.~~

(iii) For a project that involves ~~nursing home, hospital, or psychiatric~~ beds~~; hospital beds used to provide neonatal intensive care, including special newborn nursing services;~~ ~~or~~ surgical services, **either:**

(A) the signing of a~~n enforceable~~ contract for the construction, renovation, ~~or acquisition~~ **purchase or lease of equipment or** ~~necessary to develop~~ space to house the beds or operating rooms, ~~as applicable,~~ or;

(B) the licensure or certification of the beds or operating rooms for use, whichever occurs first.

(iv) For a project that involves capital expenditures other than projects specified in paragraphs (i) to (iii) of this subdivision, when an obligation is incurred or, if the certificate of need expressly defines a series of obligations for discrete components to be incurred over a period of more than **one** ~~1~~ year, when **each of** the designated obligations are incurred.

(v) For a project that involves the acquisition of licensed health facilities, the issuance of **a** new license by the department~~or the Michigan department of mental health~~.

(vi) For a project that is not specified in paragraphs (i) to (v) of this subdivision, the occurrence of the implementation event as defined in the applicable certificate of need review standards.

(c) "Letter of intent" means the **department** form~~ used by the department~~**, in electronic or paper format,** to determine the **type of review and** appropriate application forms for a proposed project.

R 325.9105 Definitions; N to S.

Rule 105. As used in these rules:

(a) "Nonsubstantive review" means review of a project accepted for review under R 325.9205 and R 325.9206.

(b) "Offer," ~~for purposes of section 22205(3) of the code,~~ means to perform a procedure or serve a patient, as applicable, as authorized by a certificate of need.~~ "Offer" does not necessarily mean full compliance with the terms, stipulations, or conditions to an approved certificate of need.~~

~~(c) "Operating costs" means any of the following costs incurred by the applicant:~~

~~(i) Salaries and wages.~~

~~(ii) Employee benefits.~~

~~(iii) Professional fees.~~

~~(iv) General supplies and materials.~~

~~(v) Purchased services.~~

~~(vi) Other costs that, under generally accepted accounting principles, are not properly chargeable as capital costs.~~

~~(d) "Predevelopment expenditure" means an expenditure for limited studies, surveys, and other documentation necessary for the preparation and filing of a certificate of need application. Limited studies, surveys, and documentation shall be differentiated from extensive and specific studies, surveys, designs, plans, working drawings, specifications, and other activities necessary to implement the project for which the certificate of need application is sought.~~

(**c**~~e~~) "Qualifying project" means each application in a comparative group which has been reviewed individually and which ~~has been determined by~~ the department **determines** to ~~have~~ satisf**y**~~ied~~ all ~~of~~ the requirements of section 22225 of the code, all other applicable requirements for approval in the code and all applicable certificate of need review standards.

(d) "Recipient" means a person who validly holds a signed approved certificate of need under the code and these rules.

~~(f) "Regional certificate of need review agency" means the agency designated by the department pursuant to section 22226 of the code.~~

(**e**~~g~~) "Single project" means an activity ~~for which~~**that requires** a certificate of need ~~is required~~ or, in the case of a capital expenditure, an activity or a group of activities involving a distinct physical area or areas of a health facility or involving the same service or **similar** services ~~or department or departments~~.

(e) "Site" means the physical location and address (or legal description of property) of a covered service or beds, unless otherwise defined in the applicable certificate of need review standards.

R 325.9109 Terms defined in code and certificate of need review standards; establishment of certificate of need review standards.

Rule 109. (1) Terms defined in the code and certificate of need review standards have the same meanings when used in these rules.

(2) All certificate of need review standards used in ~~making determinations on~~ **deciding** applications under these rules ~~shall~~**must** be established ~~pursuant to~~**by** law.

R 325.9121 Computation of time deadline.

Rule 121. ~~If a~~ **A**ny ~~time~~ deadline fall**ing**~~s~~ on a nonworking day, ~~the deadline shall~~ **will** be extended to the next department working day.

R 325.9123 Designated application dates.

Rule 123. (1) The designated application date is the date **that the department sets as the deadline for submitting applications for** ~~on which an application hall be considered as submitted to the department for purposes of commencing the review of~~ a certificate of need ~~application~~. **An application will be considered timely if it is received at the department's Lansing office and date and time stamped as received before 4:00 p.m. on a designated application date.** An application received**, including electronic submissions,** at the department's Lansing office~~s~~ after ~~5~~ **4:00** p.m. on a designated application date ~~shall~~ **will** not be considered timely and ~~shall~~ **will** be deemed submitted on the next designated application date.

(2) For an applicant seeking a nonsubstantive review under R 325.9205 and R 325.9206, the

designated application date ~~shall be~~**is** the department working day ~~on which~~ **that the department received** the application~~ is received by the department~~.

(3) For an application that is not eligible for nonsubstantive review and not subject to comparative review, the designated application date ~~shall be~~ **is** the first department working day of each month.

(4) For an application that is subject to comparative review, the designated application dates ~~shall be~~ **are** February 1~~, June 1,~~ and ~~October~~ **August** 1 of each year.

(5) An application will not be considered submitted to the department until it is submitted to the appropriate regional certificate of need review agency.

R 325.9125 Extensions.

Rule 125. The department may ~~grant an extension to~~ **extend** the date **to issue** a proposed or final decision ~~shall be issued for~~ **on** an application **for not less than 30 days but not more than 90 days** either ~~pursuant to~~ **under** R 325.9229 or upon receipt of a written request from an applicant**. (1) An applicant's written request for an extension must** ~~that~~ specif**y** ~~ies~~ either ~~a~~ **the** date or number of days being requested **for an extension. The department may extend the date to issue a proposed or final decision** if~~, in either case, all of the following requirements, as applicable, are met~~:

(i) The extension will not result in a delay in the start of the review of similar applications filed subsequently as provided by R 325.9207(2)(**b**~~a~~)**; or**~~.~~

(ii) ~~If~~**All applicants in the comparative group, for** ~~an~~ application**s** ~~is~~ subject to comparative review, ~~all applicants in the comparative group~~ request an extension of the same duration.

(~~iii~~) **(2)** ~~The extension requested is for not less than 30 days, but not more than 90 days.~~ **The department has the discretion to grant an extension for longer than 90 days, if the applicant provides justification that the department considers satisfactory. The department's decision to deny an extension request is not subject to administrative hearing or appeal.**

PART 2. APPLICATIONS; REVIEWS

R 325.9201 Letters of intent; applications; forms; copies; attachments and supplements; content; completeness; additional information; department's authority to consider relevant information not limited; notification of information considered relevant; public availability.

Rule 201. (1) ~~A person~~ **Before** applying for a certificate of need for a project, except for projects that are covered by section 22235 of the code, ~~shall~~ **a person must** ~~simultaneously~~ submit a letter of intent **simultaneously** to the department and the appropriate regional certificate of need review agency. The letter of intent ~~shall~~ **must** be on a form supplied by the department. Within 15 days of receipt of a letter of intent, the department~~, after consultation with the appropriate regional certificate of need review agency,~~ ~~shall~~ **must** notify the person proposing the project ~~of~~ whether the project requires a certificate of need and, if so, **the type of review (nonsubstantive, substantive, potential comparative) and** ~~shall~~ provide the applicant with appropriate forms. **The department will not process a letter of intent if the same covered service or beds already exists at that site under a different entity that has submitted a letter of intent or application or has previous certificate of need approval**

before the new letter of intent. ~~An application form supplied by the department may be submitted at any time. A person may request an informational copy of an application form at any time.~~ **The department will not review any application it receives before the department finishes processing the letter of intent for that application.** A letter of intent ~~shall~~ expire**s** if an application has not been submitted to the department **within one** ~~1~~ year ~~after~~ **of** receipt of the letter of intent by the department. The department ~~also shall~~**must** provide the applicant ~~and any person requesting certificate of need review standards~~ with a copy of the current work plan of the certificate of need commission~~. The work plan shall~~ indicat**ing**~~e~~ the timing which the certificate of need review standards are being revised or are scheduled to be revised by the commission~~, an explanation of when and how the work plan is periodically modified by the commission, and how an individual can be notified of all commission meetings~~.

(2) At the time of submission of an application, a person applying for a certificate of need ~~shall~~ **must** simultaneously submit **three** ~~3~~ copies of a**n** ~~completed~~ application**, or three copies of any supplemental documents for an electronic application,** for a single project to the department and**, if applicable,** ~~not more than 3~~ **one** additional ~~copies~~ **copy to** ~~as required by~~ the appropriate regional certificate of need review agency. ~~An application shall not be considered submitted to the department until it is submitted to the appropriate regional certificate of need review agency. For mental health services, 4 copies of a completed application shall be submitted.~~ The application ~~shall~~ **must** be made on the application forms authorized and provided by the department. The application forms may include requirements for attachments and supplements specified by the department in the forms. ~~An applicant may submit information prepared or collected for other purposes as an attachment.~~ An application ~~shall~~ **must** clearly state the persons, buildings, and properties to which it applies and clearly define the scope, nature, cost,~~&~~ time limits, and other aspects of the proposal~~ in the data included in and with the application as specified by the department in theapplication forms~~. A letter of intent, application, or an amendment to an approved certificate of need ~~shall~~ **must** be accompanied by the fee, if any, required by law **and these rules**. A letter of intent or an amendment not accompanied by the required fee, if any, ~~shall~~ **will** not be processed ~~by the department~~ until the **bureau receives the** required fee, if any~~, is received~~. An application not accompanied by the required fee ~~shall~~ **will** not be considered timely and ~~shall~~ **will** be deemed submitted on the next designated application date after receipt of the required fee**. An application received, including electronic submissions, that does not include statements addressing each of the review criteria listed in section 22225 of the code will not be considered timely and will be deemed submitted on the next designated application date after receipt of the required documents. Statements addressing section 22225 are not required for proposed projects eligible for nonsubstantive reviews under R 325.9205.**

(3) The department ~~shall~~ **must** consider only those applications that ~~are~~ **it deems submitted** ~~filed~~ on or before the designated application date and~~ with the advice of the appropriate regional certificate of need review agency, shall~~ **must** determine whether the application is complete~~ or incomplete~~. The department ~~shall~~ **has the right to request additional information and** provide notification of a determination to the applicant and the appropriate regional certificate of need review agency within 15 days of receipt of the application. The applicant ~~shall have~~**has** 15 days from receipt of the department's notice to **respond to the request to the department's satisfaction**~~provide additional information or otherwise complete the application~~. If **the department does not request** additional information~~ is not~~

~~requested by the department or the appropriate regional certificate of need review agency~~, the department ~~shall~~ **will** consider the application to be complete as submitted by the applicant on ~~or before~~ the designated application date. If additional information is requested, the department ~~shall~~ **will** consider the application to be complete ~~as submitted by the applicant~~ on ~~or before~~ the **next** designated application date with **or without the additional information**~~the addition of any information provided by the applicant on or before the end of the time period for submission of additional information established in this subrule~~.

~~(4) The department, within 15 days of the designated application date, shall have the right to request additional information regarding an individual application to assist in determining whether substantive or nonsubstantive review is indicated and to assist in determining the necessity for comparative review. When the additional information requested is not provided within 15 days or is inadequate, as determined by the department, the department shall make a decision based on the information available.~~

(~~5~~) **(4)** This rule ~~shall~~ **does** not limit the department's authority to consider all available information relevant to the department's review of an application.

(5) An applicant may request, and the department may allow, the submission of information after the date the application is deemed complete if the application is not subject to comparative review and if the applicant authorizes an extension to the date a decision must be issued.

(6) The department's review ~~shall~~ **must** be conducted using the completed application and **any** other information **the department considers** relevant to the decision and ~~pursuant to~~**under** all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(7) Before issuing a proposed decision, the bureau ~~shall~~ **must** notify an applicant of ~~other~~ **all** information ~~upon which it~~ **that the department** relied **upon** in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department ~~shall~~ **must** cite in the proposed or final decision letter, as applicable, ~~what~~ **the** information ~~was~~ **it** relied ~~on~~**upon**. The department ~~shall~~ **must** make ~~all other~~**this** information available to the public upon request.

(8) The department's decision to request additional information is not subject to administrative hearing or appeal.

~~R 325.9203 Determination of covered capital expenditures.~~ **Rescinded.**

~~Rule 203. (1) For purposes of determining whether a capital expenditure is a covered capital expenditure in excess of the threshold for review under the code, predevelopment expenditures shall not be included.~~

~~(2) A site acquisition or a donation shall not be considered a covered capital expenditure until it is dedicated to be used to undertake an activity for which a certificate of need is required.~~

R 325.9204 Data and physician commitments.

Rule 204. **(1)** If a certificate of need review standard requires ~~the~~**a data** commitment**, including** ~~of~~ Michigan inpatient data base **(MIDB)** ~~information~~**data or cancer registry data**, ~~in order for the department to consider a data commitment,~~ the **health facility or freestanding facility** ~~hospital~~ committing the data ~~shall~~**must** be regularly admitting patients

~~and~~**or** providing services as of the date the director makes the final decision on an application under section 22231 of the code. Further, the department ~~shall~~**must** not consider any commitment ~~of Michigan inpatient data base information~~ if a **health facility or freestanding facility** ~~hospital~~ withdrew its commitment before the final decision on an application.

(2) If a certificate of need review standard requires a physician commitment:

(a) The commitments must be submitted at the time the application is submitted to the department.

(b) A commitment must not be withdrawn after the date an application is deemed complete by the department and after a proposed decision to approve an application has been issued by the department.

(c) The department will not consider any commitment submitted by an applicant after the date an application is deemed complete by the department, unless the applicant is notified by the department that one or more of the original commitments is determined invalid according to the applicable review standards.

(d) If an applicant is notified that one or more physician commitments is determined invalid by the department, the department will consider commitments submitted after the date an application is deemed complete only to the extent necessary to replace the invalid commitments.

R 325.9205 Nonsubstantive reviews; eligibility**.**

Rule 205. (1) A person may submit a~~n~~ **letter of intent** ~~application~~ requesting a nonsubstantive certificate of need review. ~~on a form supplied by the department.~~

(2) The department~~, with the consultation of the appropriate regional certificate of need review agency,~~ ~~shall~~**must** approve the request as appropriate when the department is satisfied~~, based on the information supplied on the form supplied by the department and other information made available to it,~~ that all of the following conditions have been met:

(a) The completed project will not result in any of the following:

(i) An increase in the number of beds licensed to the applicant at the licensed site at which the project is proposed.

(ii) The initiation or expansion of a covered clinical service.

(iii) Beginning operation of a new health facility at a site that is not currently licensed for that type of health facility.

(iv) A covered capital expenditure in excess of a covered capital expenditure as defined in the code.

~~(b) The completed project will meet an already demonstrated and established need as provided by section 22225(1) of the code.~~

(~~c~~) **(b)** The proposed project is not subject to comparative review ~~pursuant to~~ **under** the code or the applicable certificate of need review standards.

(3) The department ~~shall have~~ **has** the right to accept other projects for nonsubstantive review ~~pursuant to~~ **under** section 22233 of the code. The department ~~shall~~**must** maintain~~, and provide a copy of on request,~~ a **public** list of the types of projects eligible for nonsubstantive review under this rule.

R 325.9206 Nonsubstantive review; procedure; time for decision; notice; effect of denial of request for review; department decision to deny review not subject to administrative appeal; review period; submittal of regional certificate of need review agency's recommendations.

Rule 206. (1) The department ~~shall~~ **must** ~~, after seeking the advice of the appropriate regional certificate of need review agency,~~ determine whether an application **submitted for** ~~requesting~~ nonsubstantive review is complete as provided by R 325.9201(3)~~ and shall concurrently determine whether the application is accepted for nonsubstantive review~~. The department ~~shall~~**must** notify the applicant of its decision and send a copy of the decision to the appropriate regional certificate of need review agency. The department's decision to deny nonsubstantive review of a project is not subject to administrative hearing or appeal.

(2) If a request for nonsubstantive review is denied, the application ~~shall~~**will** be deemed submitted for the purposes of substantive review on the **next designated application date after the** date of denial and the time frames to determine completeness for substantive review ~~shall~~**must** be those set forth in R 325.9201(3).

(3) The department must consider only those applications that are filed on or before the designated application date and will determine whether the application is complete or incomplete. The department must provide notification of a determination to the applicant and the appropriate regional certificate of need review agency within 15 days of receipt of the application. The applicant has 15 days from receipt of the department's notice to provide additional information or otherwise complete the application. If additional information is not requested by the department, the department will consider the application to be complete as submitted by the applicant on the designated application date. If additional information is requested, the department will consider the application to be complete on the date the department receives the applicant's responses. If the additional information requested is not received within 15 days, the application will be deemed complete.

~~(3)~~ **(4)** The period for the review of a nonsubstantive application ~~shall~~ **must** be 45 days from the date the application is ~~accepted for nonsubstantive review~~ **deemed complete** by the department. The appropriate regional certificate of need review agency ~~shall~~ **must** submit its recommendations with respect to a nonsubstantive application within 30 days ~~after~~ **of** the date the application is accepted for nonsubstantive review by the department so that the recommendations can be included in the department's review process. If new or revised certificate of need review standards applicable to a proposed project become effective before the issuance of a final decision by the director of the department, the review and issuance of proposed and final decisions ~~shall~~**must** be made ~~in accordance with~~ **according to** the provisions of R 325.9229.

~~(4)~~ **(5)** The department's review ~~shall~~ **must** be conducted using the completed application and **any** other information **the department considers** relevant to the decision and ~~pursuant to~~ **under** all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.**(6)** Before issuing a proposed decision, the bureau ~~shall~~ **must** notify an applicant of ~~other~~ **all** information ~~upon which it~~ **that the department** relied **upon** in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department ~~shall~~**must** cite in the proposed or final decision letter, as applicable, ~~what~~ **the** information ~~was~~**it** relied ~~on~~ **upon**. The department ~~shall~~**must** make ~~all other~~ **this** information available to the public upon request.

R 325.9207 ~~Procedures for~~ ~~s~~Substantive individual or comparative ~~project~~ review;

scheduling of reviews~~.~~; procedures.

Rule 207. (1) Projects subject to comparative review ~~shall~~**must** be designated ~~pursuant to~~**under** the provisions of section 22229 of the code or the applicable certificate of need review standards. Proposed projects that are not subject to comparative review and are not eligible for nonsubstantive review ~~shall~~ **must** be subject to substantive individual review under this subrule and not subrule (2) of this rule. The bureau ~~shall~~ **must** issue a proposed decision on a certificate of need application within 120 days ~~after~~ **of the date** an application is deemed completed ~~pursuant to~~ **under** R 325.9201(3). The appropriate regional certificate of need review agency ~~shall~~ **will** concurrently review the application and submit its recommendations to the department within 90 days ~~after~~ **of** the date the department determines the application is complete and the review period has commenced. If new or revised certificate of need review standards applicable to a proposed project become effective before the issuance of a final decision by the director of the department, the review and issuance of proposed and final decisions ~~shall~~ **must** be made ~~in accordance with~~ **according to** R 325.9229. A review ~~shall~~ **will** commence on the date an application is deemed complete by the department. The department, with the advice of the regional certificate of need review agency, ~~shall~~ **will** determine if an application filed by each applicant meets all applicable requirements for approval under part 222 of the code.

(2) ~~Both of t~~**T**he following provisions ~~shall~~ **will** apply to projects subject to comparative review **according to section 22229 of the code**:

(a) Projects can only be submitted when a planning area has a demonstrated need as of the designated application date.

(~~a~~) **(b)** Within 30 days ~~after~~**of** the date that all of the applications are deemed complete, the department~~, with the advice of the appropriate regional certificate of need review agency, shall~~ **must** place the timely applications into comparative groups and ~~shall~~ **must** notify the appropriate regional certificate of need review agency and each applicant ~~of~~ whether each comparative group will be subject to comparative review. For comparative reviews, the review period ~~shall commence~~ **begins** on the date of the notice under this subrule**.**~~, except that~~ **In cases** where a ~~proposed~~ **final** decision on a prior review of similar projects, services, or facilities in the same planning area has not yet been issued by the **director** ~~bureau~~, the review period ~~shall commence~~ **begins** only ~~upon the issuance of~~ **after** the **director issues a** ~~bureau's~~ **final** ~~proposed~~ decision on such prior review. ~~Applications which are subject to the provisions of this subrule and which are not subject to comparative review shall be reviewed individually in the same manner as a project submitted under subrule (1) of this rule, with the 120-day and concurrent 90-day review periods commencing on the date on which the department determines that the applications are not subject to comparative review.~~

(i) For each comparative group subject to comparative review, the notice ~~shall~~ **must** also include all of the following findings by the department:

(~~i~~) **(A)** The projections of need for the proposed facilities, beds, or services.

(~~ii~~) **(B)** That the total proposed facilities, beds, or services in the comparative group ~~is~~ **are** more than the projections of need.

(~~iii~~) **(C)**That the applications, when taken together, are mutually exclusive in that, under existing certificate of need review standards, the approval of 1 or more of the applications will necessarily result in the denial of other applications.

(ii) Applications that are not subject to comparative review must be reviewed individually in the same manner as a project submitted under subrule (1), with the 120-

day and concurrent 90-day review periods commencing on the date on which the department determines that the applications are not subject to comparative review, except when a final decision on a prior review of similar projects, services, or facilities in the same planning area has not been issued by the director, the review period begins only after the director issues a final decision on such prior review.

(~~b~~) **(c)** If, upon review under subdivision (a) of this subrule, the department determines that an application could fall into more than **one** ~~l [sic]~~ comparative group, the department ~~shall~~ **must** notify the applicant. The applicant ~~shall~~ **must** notify the department that the project is amended so that the proposed project involves only services, facilities, equipment, or beds relative to a single comparative group or notify the department that the project in its entirety is withdrawn. If the applicant advises the department that it is amending the application, additional information related to the amendment may be submitted ~~in accordance with~~ **according to** the provisions of R 325.9201(3). In the absence of notification by an applicant, the original application ~~shall be~~**is** subject to comparative review in the comparative group determined by the department and the portion of the application involving the other comparative group or groups ~~shall~~**will** not be considered by the department in its review of the application. The applicant may submit, ~~in accordance with~~ **according to** these rules, a separate application for the portion of the application not being considered.

(3) This rule ~~shall~~ **does** not limit the department's authority to consider all available information relevant to the department's review of an application.

(4) The department's review ~~shall~~ **must** be conducted using the completed application and **any** other information **the department considers** relevant to the decision and ~~pursuant to~~ **under** all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete. **(5)** Before issuing a proposed decision, the bureau ~~shall~~ **must** notify an applicant of ~~other~~ **all** information ~~upon which it~~ **that the department** relied **upon** in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department ~~shall~~ **must** cite in the proposed or final decision letter, as applicable, ~~what~~ **the** information ~~was~~**it** relied ~~on~~ **upon**. The department ~~shall~~ **must** make ~~all other~~ **this** information available to the public upon request.

R 325.9208 Comparative reviews; procedures.

Rule 208. (1) For a comparative group, the department, with the advice of the regional certificate of need review agency, ~~shall~~ **must** review the applications within the comparative group pursuant to the following procedure:

(a) A regional certificate of need review agency ~~shall~~ **must** concurrently review the applications and submit its recommendations to the department as soon as practicable, but not later than 90 days after the notification of the start of a comparative review.

(b) The bureau ~~shall~~ **must** concurrently review and issue a single proposed decision regarding the applications in the comparative group **subject to comparative review** as soon as practicable, but not later than 120 days after notification of the start of a comparative review. If new or revised certificate of need review standards applicable to a proposed project become effective before ~~the issuance of a final decision by~~ the director **issues a final decision** ~~of the department~~, **then R 325.9229 applies to** the review and issuance of proposed and final decisions ~~shall be made in accordance with the provisions of R 325.9229~~.

(c) The bureau, with the advice of the regional certificate of need review agency, ~~shall~~ **must** determine if the application filed by each applicant meets all applicable requirements for approval under part 222 of the code.

(d) The bureau ~~shall~~ **must** rank all qualifying projects in the comparative group as provided by the applicable certificate of need review standards and ~~shall~~**must** issue a single proposed decision to approve only those applications ranked highest that, in total, do not exceed the needs of the population as determined by section 22225(1) of the code. ~~The remaining applications in the comparative group shall be~~ **The bureau must** issue~~d~~ a proposed disapproval as part of the single decision **for the remaining applications in the comparative group**.

(2) The provisions of this rule and R 325.9207 ~~shall~~ **do** not apply to certificates of need applied for and issued under sections 22233 and 22235 of the code.

R 325.9210 Finance reviews; procedures.

Rule 210. (1) A person applying for a certificate of need for a project must provide the following information as applicable:

(a) audited financial statements for existing providers that includes balance sheet, income statement, statement of cash flow, and footnotes to the financial statements;

(b) evidence of secured capital funding for new providers;

(c) verification for all sources of funds dated within 30 days of submission of the application;

(d) signed vendor quote dated within six months of application submission for applications involving medical equipment;

(e) all applicable lease and purchase agreements;

(f) designated funds must specify what type of funds are used (e.g., cash, bond, etc.); and

(g) the market value for any asset must be verifiable by an unrelated party.

(2) For construction projects, the applicant will competitively bid capital expenditures among qualified contractors or alternatively, the applicant is proposing an alternative to competitive bidding that will achieve substantially the same results as competitive bidding.

(3) An applicant utilizing future operations (e.g. capital operating lease) as a source of funds must demonstrate the following:

(a) current bank or financial institution statement or balance and dated within 30 days of submission of the application,

(b) third party verification of a bank loan, HELP loan, or other equivalent source of funding.

(4) The department's finance review must be conducted using the completed application and any other information the department considers relevant to the decision and under all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(5) Before issuing a proposed decision, the bureau must notify an applicant of all information that the department relied upon in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department must cite in the proposed or final decision letter,

as applicable, the information it relied upon. The department must make this information available to the public upon request.

(6) This rule does not limit the department's authority to consider all available financial information relevant to the department's review of an application.

R 325.9215 Amendments to applications before a proposed decision is issued by the bureau.

Rule 215. (1) An **applicant cannot amend an** application ~~scheduled~~ **subject** ~~for~~ **to a** comparative review ~~shall not be amended~~ after the designated application date established ~~pursuant to~~ **under** R 325.9123, except to the extent that additional information is requested by the department to make the application complete ~~pursuant to~~ **under** R 325.9201 or R 325.9229(6) or as provided for in R 325.9207(2)(b). A person desiring to amend an application ~~shall~~ **may: (a)** ~~have the choice of~~ withdraw~~ing~~ the amendment**, (b)** ~~or~~ have**e**~~ing~~ the project considered under a new application on a subsequent designated application date**, or (c) if the application is subject to comparative review, amend the application if all applicants in the comparative group agree to allow an amendment as long as the amendment(s) do not increase the scope of the project**.

(2) An amendment cannot modify the person, the building or the purpose of the property.

(3) A request to amend an application must be accompanied by the required fee if the amendment request results in higher costs under the fee schedule in section 20161 of the code for the proposed project that would have required a higher application fee when submitted originally. An amendment not accompanied by the required fee will not be processed by the department until the required fee is received.

(~~2~~) **(4)** An application that is not subject to comparative review may be amended by the applicant up to 30 days in advance of the proposed decision date established by these rules. If the department, with the advice of the appropriate regional certificate of need review agency, determines that the proposed amendment substantially changes the original application and that additional review by the department and the regional certificate of need review agency is required to adequately evaluate the proposal ~~in accordance with~~ **according to** the code and these rules, the department ~~shall~~ **will** require, as a condition of the amendment, that the applicant agree to extend the date for proposed decision as required to permit the additional review.

(~~3~~) **(5)** The department may consider new or revised information submitted by an applicant, for an application that is not being reviewed on a comparative basis, within 30 days of the proposed decision date, or at any time after the proposed decision and before a final decision is issued, if an applicant requests an extension to the proposed or final decision date sufficient to allow the department, and the appropriate regional certificate review agency, up to 30 days to review the new or revised information. The department may request from an applicant a longer extension, if necessary, to review new or revised information. The applicant ~~shall~~ **must** also simultaneously submit the new or revised information to the appropriate regional certificate of need review agency. The department ~~shall~~ **must** make the new or revised information available to the public upon request.

(~~5~~) **(6)** If an applicant for a project not originally subject to comparative review proposes to amend the application in such a way as to make it subject to a comparative review, the **bureau must notify the** applicant ~~shall be notified~~ of the need for comparative review**. The applicant may then either** ~~and shall have the choice of~~ withdraw~~ing~~ the amendment or

have~~ing~~ the project considered under a new application on a subsequent designated application date.

R 325.9227 Emergency review; request; denial~~; submission of formal application~~.

Rule 227. (1) A request for an emergency certificate of need review under section 22235 of the code may be made ~~by telegram~~ **electronically** or **in paper format**~~other abbreviated written form~~. The request ~~shall~~ **must** include justification for the project and a statement of the nature and extent of the claimed emergency.

(2) If the department determines that a request filed under subrule (1) of this rule is not covered by section 22235 of the code, it ~~shall~~ **must** ~~so~~ inform the applicant, in writing, within 10 working days of receipt of the request**,** and ~~shall~~ deny the request for emergency review. ~~Pursuant to section 22235 of the code, an applicant for a project granted emergency approval shall submit a formal application for a certificate of need within 30 days of the requested emergency review.~~

(3) The department's decision to deny emergency review is not subject to administrative hearing or appeal.

R 325.9228 Short-term nursing care program (swing bed) review; maximum number of patient days variation.

Rule 228 (1) A request for a short-term nursing care program certificate of need review under section 22210 of the code may be made electronically or in paper format. The request must include justification for the project and demonstration of compliance with the requirements set forth in section 22210 of the code.

(2) Evidence that the hospital has had difficulty in placing patients in skilled nursing home beds during the 12 months immediately preceding the date of application must include, but not limited to, that the average occupancy rate for all existing and operating nursing homes within a 20 mile radius of the hospital has been at least 85% for the last four (4) quarters based upon the department's Staffing/Bed Utilization Ratios Report.

(3) The department may grant a one year variation from the maximum number of patient days established under subsection (3)(e) of section 22210 of the code if the applicant demonstrates immediate need for the project by showing the average occupancy rate for all existing and operating nursing homes within a 100 mile radius of the hospital has been at least 85% for the last four (4) quarters based upon the department's Staffing/Bed Utilization Ratios Report.

R 325.9229 New or revised certificate of need review standards approved by certificate of need commission.

Rule 229. (1) ~~Pursuant to section 22215(4) of the code, new or revised certificate of need review standards shall apply to the review of all certificate of need applications for which the director of the department has not issued a final decision as of the effective date of the new or revised certificate of need review standards.~~

~~(2) Applications pending a final decision by the director of the department at the time new or revised certificate of need review standards become effective shall be considered as having been submitted subject to the new or revised certificate of need review standards and shall be processed in accordance with subrule (3), (4), (5), or (6) of this rule, as applicable~~. **If**

the department issues new certificate of need standards or revises certificate of need standards between the time an application is filed and when the director issues a final decision on the application, then the bureau must consider and process the application according to this subrule.

(~~3~~) **(2)** If **the bureau is reviewing** an application~~ is being reviewed~~**, other than on a comparative review basis,**~~ on a substantive individual basis~~ and the bureau has not issued a proposed decision ~~as all of~~**before** the effective date of the new or revised certificate of need review standards**:**~~,~~

(a) ~~t~~**T**he applicant, within 15 days of the effective date of the new or revised certificate of need~~ed~~ review standards, may request, and the department ~~shall~~ **may** grant, an extension **(under R 325.9125)** of the date by which a proposed decision must be issued by the bureau under these rules and the code. During the extension period, the applicant may submit to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that the application ~~is in~~ compli**es**~~ance~~ with the new or revised certificate of need review standards**;**~~.~~

(b) If an **applicant requests an** extension **under this rule** ~~to submit additional information is requested~~, the bureau ~~shall~~ **must** issue a proposed decision on the completed application, ~~including any additional information submitted pursuant to this subrule in accordance with~~ **using** the new or revised certificate of need review standards, on or before **45 days for nonsubstantive applications or** 120 days **for substantive applications,** after receipt of the additional information**;**~~.~~

(c) If the applicant does not ~~make a~~ request **an extension** under this ~~sub~~rule, the bureau ~~shall~~ **will** issue a proposed decision on the completed application reviewed ~~in accordance with~~ **according to** the new or revised certificate ~~all~~ of need standards and the proposed decision ~~shall~~ **will** be issued ~~in accordance with~~ **according to** the date established ~~pursuant to~~ **under** R 325.9207.

(4) If **the bureau has reviewed** an application~~ is being reviewed~~**, other than on a comparative basis,**~~ on a substantive individual basis,~~ and the bureau has issued a proposed decision**:**~~,~~

(a) ~~t~~**T**he applicant may request, within 15 days of the effective date of the new or revised certificate of need~~ed~~ review standards, and the department ~~shall~~ **may** grant, a remand of the ~~review~~ **proposed decision** to the bureau. Upon such remand, the date a final decision must be issued by the director of the department is stayed and the applicant may submit, to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that the application ~~is in~~ compli**es**~~ance~~ with the new or revised certificate of need review standards **under R 325.9125**. Upon remand, the bureau ~~shall~~ **must** issue a proposed decision on the completed application~~, including any additional information submitted pursuant to this subrule in accordance with~~ **according to** the new or revise**d** ~~[sic] the~~ certificate of need review standards, on or before **45 for nonsubstantive applications or** 120 days **for substantive applications,** after receipt of the additional information**;**~~.~~

(b) I**f**~~t~~ the applicant does not ~~make a~~ request **a remand** under this ~~sub~~rule, the director of the department ~~shall~~**will** issue a final decision on the completed application reviewed ~~in accordance with~~**according to** the new or revised certificate of need standards and the final decision ~~shall~~ **will** be issued in accordance with the date established ~~pursuant to~~ **under** these rules and the code.

(5) If **(i) the bureau has reviewed** an application~~ is being reviewed~~**, other than on a**

comparative basis; ~~on a substantive individual basis, and~~ **(ii)** the bureau has issued a proposed decision**;**~~,~~ and **(iii)** the applicant has requested a hearing on a proposed decision ~~pursuant to~~ **under** section 22232(1) of the code, **then,** regardless of the stage of the hearing**:**~~,~~

(a) the applicant may request that the matter be remanded to the bureau for further review ~~in accordance with~~ **according to** subrule (3) of this rule**;** ~~or,~~

(b) if the applicant does not ~~make a~~ request **a remand** under this subrule, the applicant ~~shall be allowed~~ **may, within** 60 days following the effective date of the new or revised certificate of need review standards**,** ~~to~~ augment, for introduction in the hearing, its testimony, evidence, and exhibits in support of its application with regard to the new or revised certificate of need review standards**;**~~.~~

(c) If an applicant does not ~~make a~~ request ~~for~~ a remand under this subrule, the department ~~shall~~**must** submit, to the hearing officer, within 60 days of the effective date of the ~~k~~new ~~[sic]~~ **or** revised certificate of need review standards or 60 days ~~after~~ **of the date** an applicant has augmented the record, whichever comes later, an analysis of the applicant's compliance with the new or revised certificate of need review standards.

(6) If an application is in a comparative review, regardless ~~of~~ whether it is in the process of being reviewed by the bureau or, in any stage of a hearing, by the director of the department, any applicant in the comparative group, within 15 days ~~after~~**of** the effective date of the new or revised ~~[sic]~~ certificate of need standards, may request, and the department ~~shall~~**may** grant~~, either~~ an extension ~~or a remand and extension to the bureau~~ to review and issue a proposed decision on the comparative group ~~in accordance with~~ **according to** the new or revised certificate of need review standards. Upon extension or remand and extension, each applicant in the comparative group ~~shall be considered as having made the request and shall be permitted~~ **may submit, within** 60 days **following the effective date of the new or revised certificate of need review standards** ~~to submit~~, to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that its application ~~is in~~ compli**es**~~ance~~ with the new or revised certificate of need review standards. Upon such an extension or remand and extension, the bureau ~~shall~~ **will** issue a single proposed decision on the completed applications, with the addition of any information submitted ~~pursuant to~~ **under** this subrule from the comparative group ~~in accordance with~~ **according to** the new or revised certificate of need review standards, on or before 120 days ~~after~~ **of** the last date on which additional information may be submitted under this subrule. If none of the applicants request an extension or a remand and extension, for the review and issuance of a single decision on the comparative group ~~shall~~ **will** be based on each completed application reviewed ~~in accordance with~~ **according to** the new or revised certificate of need standards and the decision ~~shall~~ **will** be issued ~~in accordance with~~ **according to** the date established ~~pursuant to~~ **under** these rules and the code.

(7) The ~~department~~**bureau** ~~shall~~**must** consider the recommendation of the appropriate regional certificate of needed review agency, if the recommendation is received ~~**not**~~ more than 30 days before the bureau or department decision dates established ~~pursuant to~~**under** this rule.

~~(8) After the director has issued a final decision to disapprove an application that is not subject to comparative review, an applicant main [sic] submit, within 60 days of the final decision date, and the department may accept, additional information to demonstrate a need for the project pursuant to section 22225(1) of the code. An applicant shall also simultaneously submit any additional information to the appropriate regional certificate of~~

~~need review agency. If new or revised certificate of need review standards applicable to the project become effective after the final decision is issued by the director, and if an applicant submits additional information to demonstrate a need for the project for which the disapproval was issued, the director's reconsideration shall be based on the new or revised certificate of need review standards.~~

~~(9) If an applicant submits additional information pursuant to subrule (8) of this subrule, the department shall incorporate the additional information into the department's file for that application.~~

~~(10) If an applicant submits additional information pursuant to subrul (8) [sic] of this subrule, and if the department determines that an application is in compliance with the requirements for approval in the code and the new or revise [sic] to certificate of need review standards, the bureau shall issue a revised proposed decision and the director shall issue date revised final decision in accordance with the applicable procedures for scheduling reviews and decisions set forth in the code and these rules for the type of review applicable to the project.~~

PART 3. APPROVAL AND ISSUANCE; DISAPPROVAL

R 325.9301 Bureau and department decision to be written; issuance of one ~~1~~ decision for all applications in comparative review; conditions and stipulations as integral parts of certificate of need; request for hearing deemed request for hearing on entire decision; issuance of final decision**.**

Rule 301. (1) The ~~certificate of need~~ **bureau will issue only one** proposed ~~and final~~ decision~~s~~ **for all applications, including qualifying and nonqualifying projects, when a comparative group is determined to be subject to comparative review** ~~shall be in writing~~.

(2) The ~~bureau and department~~**director** ~~shall~~**will** issue only **one** ~~1~~ decision for all applications, including qualifying and nonqualifying projects, ~~in~~ **when** a comparative ~~**review**~~ **group is determined to be subject to comparative review**.

(3) ~~Conditions and stipulations are integral parts of the certificate of need.~~ A request for hearing filed ~~pursuant to~~**under** section 22231 or 22232 of the code related to any part of a decision**, including conditions and stipulations,** ~~shall~~ **will** be deemed a request for hearing on the entire decision.

(4) The director ~~of the department shall~~ **must** issue a final decision ~~pursuant to~~ **under** all applicable requirements and provisions of the code.

R 325.9303 Effective date of certificate.

Rule 303. Unless otherwise specified ~~by the department~~ **in the final decision**, a certificate of need ~~shall be~~**is** effective on the date the **director issues the** final **decision** ~~approval is issued by the director~~.

PART 4. TERMS AND CONDITIONS

R 325.9401 Validity of certificate**.**

Rule 401. (1) A certificate of need ~~shall~~ **will** be valid only as long as there is compliance

with the provisions in the final or amended application, including project timetables, except as expressly modified in the certificate of need and ~~the~~ **its** amendments ~~thereto~~.

(2) ~~As provided by section 20164(2) of the code, the certificate of need is not transferable and shall be valid only for the persons, buildings, and properties stated in the certificate.~~ **The recipient of a certificate of need must comply with all provisions of:**

(a) the certificate of need,

(b) amendments to the certificate of need, and

(c) the application to the extent it has not been modified by the certificate of need and its amendments.

(3) Only the persons authorized by the certificate of need may offer the covered clinical services or beds listed in the certificate of need.

R 325.9403 Term of certificate.

Rule 403. (1) Unless otherwise specified in a certificate of need review standard **or final decision**, a certificate of need ~~shall~~ expire**s** **one** ~~1~~ year from its effective date, unless the project is implemented as defined in R 325.9103(b).

(2) The ~~department~~ **bureau**, upon written request of the ~~applicant~~ **recipient**, ~~shall have~~ **has** the right to extend the implementation period established in subrule (1) of this rule or in a certificate of need review standard by not more than **six** ~~6~~ months if ~~all of the following provisions are satisfied~~ **the bureau determines that**:

(a) The terms of the certificate are not changed~~.~~**;**

(b) Substantial progress has been made~~.~~**; and**

(c) ~~If applicable, an obligation for capital expenditure or establishment of a force account is likely to~~ **The requirements of R 325.9103(b) will** occur within the extended time period.

(3) Any extension granted under subrule (2) does not change the effective date of the certificate of need.

(~~3~~) **(4)** **At any time,** ~~T~~**t**he department **may request, and the person holding the certificate of need must immediately provide, any** ~~has the right to make unscheduled periodic reviews and surveys of the project for which a certificate of need is issued and all related~~ documentation**, including project schedules,** to determine whether ~~progress is being made in accordance with~~ the project **is on schedule and within the**~~timetable and~~ estimated costs ~~of~~**for** the project.

(~~4~~) **(5)** For projects subject to the provisions of R 325.9103(b)(i), (ii) or (vi), a certificate of need review standard may establish a term of the certificate other than as established in subrules (1) and (2) of this rule, in which case the certificate of need ~~shall~~ expire**s** at the end of the time period specified in the standard.

R 325.9413 Amendments to approved certificates of need.

Rule 413. (1) A~~n~~ ~~applicant~~ **recipient** may ~~make a written~~ request ~~to~~ the department ~~for an~~ **to** amend~~ment to~~ an approved certificate of need if the project is not a completed project. ~~If the approved certificate of need involves mental health services, a copy of the request and all subsequent information submitted to the department shall simultaneously be submitted to the Michigan department of mental health.~~ After consult~~ation~~**ing** with the appropriate regional certificate of need review agency, **the department must decide** ~~a determination shall be made by the department~~ whether the amendment ~~does or does not~~ require**s** another review. The department's decision to require another review **or deny a request is**~~shall~~ not ~~be~~ subject

to the administrative hearing process set forth in Act No. 306 of the Public Acts of 1969, as amended, being §24.201 et seq. of the Michigan Compiled Laws. A certificate of need issued after a comparative review ~~shall~~ **can**not be amended to ~~increase~~ **change** the scope of the project or to increase the cost of the project. A certificate of need issued after a comparative review ~~shall~~ **can**not be amended to change the method of financing the project, or the terms of financing the project, except where a~~n applicant~~ **recipient** demonstrates, to the satisfaction of the department, an amendment to change the method or terms of financing offers a less costly alternative to the approved method or terms of financing the project. **An amendment cannot change the site of an approved health facility or covered clinical service or increase the number of beds or covered clinical services approved in a certificate of need.** Unless waived by the department, amendments to a certificate of need ~~shall be~~ **are** subject to the same conditions and stipulations imposed on the original certificate~~.~~**, and any new conditions and stipulations imposed on the amendment.**

(2) A request to amend a certificate of need must be accompanied by the required fee if the amendment request results in higher costs under the fee schedule in section 21601 of the code for the proposed project that would have required a higher fee when submitted originally. An amendment not accompanied by the required fee will not be processed by the department until the required fee is received.

(~~2~~) **(3) The department may allow** ~~A~~**a**n amendment ~~authoriz~~**request**ing a change in the method and terms of financing, approved capital expenditures **(e.g. medical equipment)**, or ~~operating~~**other** costs ~~shall be made~~ only in those instances where the ~~facility~~**recipient** is able to demonstrate that the need for amendment arises from circumstances beyond its control or the amendment offers a better alternative as determined by the department with the advice of the appropriate regional certificate of need review agency.

~~(3) A completed project shall not be amended.~~

(4) An amendment cannot modify the person, the building or purpose of the property.

~~(4)~~ **(5)** The department may request additional information regarding a proposed amendment ~~pursuant to~~**under** the time periods set forth in R 325.9201(3).

~~(5)~~ **(6)** The review period for a request to amend an approved certificate of need ~~shall~~ **must** not be longer than the original review period for the application. **When reviewing a proposed amendment to an approved certificate of need, the bureau must use the standards in effect at the time of the original approval of the certificate of need.**

(7) The department may grant an extension to the date a decision will be issued for an amendment upon written request from a recipient. An extension may be granted for not less than 30 days, but not more than 90 days.

R 325.9415 Amendment to approved certificates for an increase in project costs.

Rule 415. ~~Due to the difficulty in estimating, in advance, finance costs, construction delays, the need for minor construction change orders, and other similar unforeseeable events, a~~ **A**n amendment to an approved certificate of need for increased project costs ~~shall~~**will** not be required if the total amount of excess does not exceed the sum of 15% of the approved project costs up to $1,000,000.00 and 10% of the approved project costs in excess of $1,000,000.00.

R 325.9417 Certificate timetables.

Rule 417. (1) An application for a certificate of need ~~shall~~ **must** specify the timetable the

applicant will follow in making the health facility, beds, services or equipment available or for beginning and completing construction.

(2) The **recipient must** ~~period of time allowed to~~ begin ~~any~~ construction ~~shall be not more than~~ **within** 24 months ~~from~~ **of** the effective date of ~~approval~~ **the certificate of need.**~~, except that t~~ **A recipient may request to extend to begin any construction beyond the 24-month period, with an amendment request to the department. T**he department may approve **to extend the** ~~a longer~~ period of time **to begin construction** ~~through written amendment to the certificate of need~~ if the department determines that circumstances justify an extension. **Extending the 24-month period does not change the effective date of the certificate of need.**

(3) The recipient must install the medical equipment specified in the certificate of need within 24 months of the effective date of the certificate of need. A recipient may request to extend an installation beyond the 24-month period, with an amendment request to the department. The department may approve to extend the period of time for installation if the department determines that circumstances justify an extension. Extending the 24-month period does not change the effective date of the certificate of need.

(4) For medical equipment, the first procedure must be performed within three (3) months of the installation date of the equipment specified in R 325.9103(b)(ii). The department may approve to extend the period of time for the first procedure to be performed if the department determines that circumstances justify an extension. This does not change the effective date of the certificate of need.

R 325.9419 Monitoring compliance with approved certificates of need ~~pursuant to~~under section 22247 of the code.

Rule 419. (1) ~~Upon a determination by~~ **If** the department **determines** ~~and~~ **that a** ~~applicant~~ **recipient** ~~is not in compliance~~ **has not complied** with the terms, conditions, or stipulations of an approved certificate of need, the department ~~shall~~ **will** notify the ~~applicant~~ **recipient**. The department ~~shall~~ **will** also specify the period of time during which the noncompliance occurred. ~~The applicant shall notify all payers of services provided by the applicant that the approved services are not being provided in compliance with the terms, conditions, or stipulations of an approved certificate of need.~~

(2) In determining the appropriate action to take ~~in accordance with~~**according to** section 22247(2) of the code, the department ~~shall~~ **will** consider the extent and duration of the noncompliance.

(3) The department ~~shall~~ **must** make available, to the public, on request, a list of all certificates of need determined not to be in compliance with the terms, conditions, or stipulations approved in a certificate of need**. If required by the department, the recipient must notify all payers of services provided by the recipient that the approved services are not being provided in compliance with the terms, conditions, or stipulations of an approved certificate of need.**

(4) The department decision is final and binding.

PART 5. ADMINISTRATIVE APPEALS

R 325.9501 Hearing request; eligibility; effect. **Rescinded.**
Rule 501. (1) An applicant that receives either of the following:
(a) a proposed decision of the bureau which disapproves 1 or more certificates of need, or
(b) a notice of reversal by the director of a proposed decision that is an approval, may request a hearing, as authorized by the code, to demonstrate that the completed application filed by the applicant meets the requirements for approval under part 222 of the code.
(2) The filing of If an applicant files a request for hearing, the department cannot issue shall stay issuance of a final decision until during the pendency of the hearing is finished before the department.

R 325.9503 Hearing procedure. **Rescinded.**
Rule 503. (1) An applicant requesting for a hearing is commenced bymust fileing a the request for hearing with the director of the department, 3423 North Martin L. King Jr. Blvd., P.O. Box 30195, Lansing, Michigan 48909 department's Administrative Tribunal Appeals Section.
(2) A request for a hearing shall must be filed within 15 days of the applicant'safter receipt of the bureau's proposed decision or receipt of notice the date of the reversal by the director of a proposed decision that is an approval.
(3) A request for a hearing shall must be made in writing and shall must include all of the following:
(a) a statement of the grounds for a hearing; and
(b) a clear and concise statement of the facts and law relied on; and
(c) the relief sought.
(4) The applicant must serve a A copy of the request for a hearing shall be served upon the appropriate regional certificate of need review agency. In addition, if the request for a hearing is filed by an applicant in a comparative review, the applicant must serve a copy of the request for a hearing hall be served by the applicant upon all other applicants in the comparative group when the request for hearing is filed.
(5) The hearing shall must commence within 90 days from the date that the department received the request for a hearing, unless waived in writing by the parties. Not less than 10 days before the date set in the notice, the department tribunal shall must serve notice of the hearing, by placing a copy of the notice in the mail to each, upon the person who filed the request for a hearing, the assistant attorney general assigned to represent the department, and all other persons on whom the request for a hearing was required to be served. The first hearing day shall will be utilized as a prehearing conference and may be used for hearing preliminary motions.
(6) If more than 1 request for a hearing is filed with respect to the same bureau decision, the hearings so commenced shall must be consolidated and shall must be heard and decided as a single hearing. A party shall must not be severed from a hearing on a comparative review.
(7) In all hearings by aggrieved applicants, the necessary parties are the department and any aggrieved applicant that perfected filed its request for a hearing in a timely manner. The bureau shall is not be required to file a response to a request for a hearing. In comparative reviews, approved applicants are necessary parties to any hearing and must receive notice of all hearings.

~~R 325.9505 Service of documents.~~ **Rescinded.**
~~Rule 505. Unless otherwise specified, service of a document upon any party shall be made by personal delivery or by mailing, by registered, certified, or first-class mail, to the last known address of the party or the authorized representative of a party as indicated on the records of the department. Proof of service shall be filed with the department.~~

~~R 325.9509 Form of hearing request.~~ **Rescinded.**
~~Rule 509. (1) A request for a hearing shall be titled "In the matter of (name of appellant or appellants)." The caption shall appear at the upper left side of the first page of each filed pleading or document other than an exhibit.~~
~~(2) The first page of a pleading or document, other than an exhibit, shall show the case number, if assigned, at its upper right side opposite the caption.~~

R 325.9513 ~~Adjournment~~. **Rescinded.**
~~Rule 513. A party may request an adjournment of a scheduled hearing by motion to the hearing officer assigned to conduct the hearing. The hearing officer shall not rule on the request until all other parties have had an opportunity to be heard on the request. However, if all parties agree to the adjournment, then the hearing officer may be advised of the agreement by telephone and may rule on the request immediately.~~

~~R 325.9517 Withdrawal of request for hearing; agreement.~~ **Rescinded.**
~~Rule 517. (1) At any time before a final decision is issued by the director of the department, a party may withdraw its application or request for a hearing.~~
~~(2) or t~~T~~he party or parties to a hearing may negotiate an agreement disposing of the whole case or a part of the case in compliance with Part 222 of the code, but that agreement is not effective unless it is approved by the department.~~

R 325.9525 ~~Issuance of final decision by the department director~~. **Rescinded.**
~~Rule 525. (1) After the conclusion of a hearing, the hearing officer, if other than the director of the department, shall deliver, to the director of the department, the official case file and the hearing officer's proposal for decision. The hearing officer shall serve the proposal for decision upon the parties by first-class or certified mail or by personal service. Each party shall have 20 days from the date of service of the proposal for decision to file exceptions or present written arguments to the director. Exceptions and written arguments shall be served on all parties, who shall have 10 days to file their replies to the exceptions with the director of the department and serve the replies on the parties.~~
~~(2) After review of the record or the proposal for decision, exceptions thereto, and replies, if any, the director of the department shall issue a final decision stating the findings of fact, conclusions of law, and the final decision or an order for further proceedings. The director of the department shall serve copies of the final decision upon all parties.~~
~~(3) All applications that are part of a comparative review shall be decided in 1 final decision.~~
~~(4) The final decision of the director of the department may be appealed only by the applicant and only on the record directly to the circuit court for the county where the applicant has its principal place of business in this state or the circuit court for Ingham~~

~~county. Judicial review shall be is governed by sections 101 to 106 of Act No. 306 of the Public Acts of 1969, as amended, being §§24.301 to 24.306 of the Michigan Compiled Laws.~~

R 325.9551 Hearing request; eligibility; effect.

Rule 551. (1) An applicant that receives either of the following:

(a) a proposed decision of the bureau which disapproves 1 or more certificates of need, or

(b) a notice of reversal by the director of a proposed decision that is an approval, may request a hearing, as authorized by the code, to demonstrate that the completed application filed by the applicant meets the requirements for approval under part 222 of the code.

(2) If an applicant files a request for hearing, the department cannot issue a final decision until the hearing is finished.

R 325.9552 Hearing procedure.

Rule 552. (1) An applicant requesting a hearing must file the request for hearing with the department's Administrative Tribunal Appeals Section.

(2) A request for a hearing must be filed 15 days after receipt of the bureau's proposed decision or the date of the reversal by the director of a proposed decision that is an approval.

(3) A request for a hearing must be in writing and must include all of the following:

(a) a statement of the grounds for a hearing;

(b) a clear and concise statement of the facts and law relied on; and

(c) the relief sought.

(4) The applicant must serve a copy of the request for a hearing on the appropriate regional certificate of need review agency. In addition, if the request for a hearing is filed by an applicant in a comparative review, the applicant must serve a copy of the request for a hearing on all other applicants in the comparative group when the request for hearing is filed.

(5) If more than 1 request for a hearing is filed with respect to the same bureau decision, the hearings so commenced must be consolidated and must be heard and decided as a single hearing. A party must not be severed from a hearing on a comparative review.

(6) In all hearings by aggrieved applicants, the necessary parties are the department and any aggrieved applicant that filed its request for a hearing in a timely manner. The bureau is not required to file a response to a request for a hearing. In comparative reviews, approved applicants are necessary parties to any hearing and must receive notice of all hearings.

R 325.9553 Reconsideration.

Rule 553. At any time during the appeals process the department may reconsider the original decision to determine compliance.

R 325.9554 Withdrawal of request for hearing; agreement.

Rule 554. (1) At any time before a final decision is issued by the director a party may withdraw its request for a hearing.

(2) The party or parties to a hearing may negotiate an agreement disposing of the whole case or a part of the case in compliance with Part 222 of the code, but that agreement is not effective unless it is approved by the department.

R 325.9555. Issuance of final decision by the department director.

(1) After review of the record and the proposal for decision, exceptions if any, and replies, if any, the director must issue a final decision stating the findings of fact, conclusions of law, and the final decision or an order for further proceedings. The director must serve copies of the final decision upon all parties.

(2) All appeals of applications that are part of a comparative review must be decided in one final decision.

(3) An applicant may appeal the final decision of the director directly to the circuit court for the county where the applicant has its principal place of business in this state or the circuit court for Ingham county. Judicial review is governed by sections 101 to 1969 PA 306, being section 24.301 to 24.306 of the Michigan Compiled Laws.

Summary of Proposed Revisions to CON Administrative Rules

The Certificate of Need (CON) Administrative Rules are used to provide additional clarification and guidance on the procedures used by the Department to process a CON application, as authorized under Part 222 of the Public Health Code. The CON Administrative Rules were last updated March 27, 1996.

Most of the proposed changes to the Rules are technical in nature to clarify ambiguity that currently exists in some of the subrules, incorporate needed changes due to changes in the Code (PA 619 of 2002), and update the rules to current Department practice (including filing an online application). More substantive changes are identified in this summary report.

The Appeals section of the Rules has been revised to conform with the Administrative Procedures Act.

Excerpts from Part 222 Relating to the Administrative Rules

MCL 333.22215 Duties of commission...(i) In accordance with section 22255, approve, disapprove, or revise proposed procedural rules for the certificate of need program.

MCL 333.22221 Duties of department generally...(a) Subject to approval by the commission, promulgate rules to implement its powers and duties under this part.

MCL 333.22255 Procedural rules...The department, with the approval of the commission, may promulgate procedural rules to implement this part.

Highlights

1. Acknowledges the fact that applications and other forms may be submitted electronically.
   (Rules 9101(b), 9103(c), 9123(1), 9201(2), 9227(1)) – **No MCL reference**

2. Changes the time on a designated application date when an application is considered timely from 5:00 p.m. to 4:00 p.m. This will avoid staff having to work overtime when processing applications received just before 5:00 p.m., which happens frequently.
   (Rule 9123(1)) – **No MCL reference**

3. Reduces the number of designated application dates for comparative review applications from three (3) to two (2) per year. This will allow more time for hearings to occur without overlapping into the next designated application date, creating better administrative efficiency.
   (Rule 9123(4)) – **MCL 333.22229**

4. Clarifies that a letter of intent must be processed by the department prior to the submission of the corresponding application.
   (Rule 9201(1)) – **No MCL reference**

5. Clarifies the authority to not deem an application submitted until statements addressing section 22225 of the code are received. Addresses the recent court case in Macomb County.
   (Rule 9201(2)) – **MCL 333.22223**

6. Formalizes the current authority to request additional information on an application.
   (Rule 9201(3)) – **No MCL reference**

7. Clarifies the physician commitment process to make it more uniform for the different covered clinical services. – **No MCL reference**
   (Rule 9204)

Highlights - continued

8. Clarifies that projects under comparative review can only be submitted when a planning area has a demonstrated need.
   (Rule 9207(2)(a)) – **MCL 333.22229**

9. Adds a rule for Finance Reviews and lists the items an applicant is required to provide.
   (Rule 9210) – **MCL 333.22225(2)(b)**

10. Allows amendments to comparative review applications prior to approval as long as all applicants in a comparative group agree to allow an amendment(s).
    (Rule 9215(1)) – **No MCL reference**

11. Clarifies that an amendment prior to approval shall not modify person, building or purpose of the property.
    (Rule 9215(2)) – **No MCL reference**

12. Requires a fee for amendments if they result in higher costs under the fee schedule for the proposed project that would have required a higher application fee when submitted originally, and that amendments shall not be processed by the department until the required fee is received.
    (Rule 9215(3), 9413(2)) – **MCL 333.22215(6), 333.20161(3)**

13. States that the department's decision to deny emergency review is not subject to administrative hearing or appeal. – **MCL 333.22235**
    (Rule 9227(3))

14. Adds a rule for Short-term nursing care program (swing bed) reviews and allows the department to grant a one (1) year variation from the maximum number of patient days required in the code, if certain requirements are met. The code gives the department the authority to develop a rule granting a variation in this number.
    (Rule 9228) – **MCL 333.22210**

15. Removes the ability to have a reconsideration of a final decision by the department director when a standard changes. The applicant can file a new application under the new standards.
    (Rules 9229(8), 9229(9), 9229(10)) – **MCL 333.22231**

16. Gives the department the authority to deny a request for an amendment after approval of an original application.
    (Rule 9413(1)) – **No MCL reference**

17. Clarifies that an amendment of an original approved application cannot change the site of an approved health facility or covered clinical service or increase the number of beds or covered clinical services approved in a certificate of need.
    (Rule 9413(1)) – **No MCL reference**

18. Clarifies that an amendment shall be reviewed under the standards in effect at the time of the original approval of the certificate of need.
    (Rule 9413(6)) – **No MCL reference**

19. Treats covered clinical equipment the same as construction in terms of granting an extension beyond the 24-month period for installation or to begin construction, if the department determines circumstances justify an extension.
    (Rule 9417(3)) – **No MCL reference**

Highlights – continued

20. Gives the department the authority to reconsider an original decision on an application, if during the appeals process an applicant can demonstrate compliance with the code and applicable review standards.
    (Rule 9553) – **MCL 333.22231**

3/9/10

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Case Name	**Date Opened**	**Case Description**	**Status**
Livingston County - Compare Group #950184 INCLUDES: Brighton Senior Care & Rehab Center #2009-5819-CON Heartland Healthcare Center II 2009-6457-CON Livingston Health Campus Livingston Care Center, LLC 2009-5815-CON Medilodge of Howell, Inc. 2009-32560-CON	12/30/08	Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The five applicants are: (1) Brighton Senior Care & Rehab Center, LLC (successful applicant), (2) HCR ManorCare Services, LLC (petitioner), (3) Trilogy Healthcare of Livingston, LLC, (4) Livingston Care Center, LLC (petitioner), and (5) MediLodge of Howell, Inc. (petitioner).	On February 8, 2010, the Director of the Department issued her Final Order determining that the ALJ's 10/9/09 Proposal for Decision was correct. No applicant appealed the final decision within the 30-day time period set forth in the statute.

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Case Name	**Date Opened**	**Case Description**	**Status**
Livingston County - Compare Group # 950195 INCLUDES: Livingston Care Center 2009-5815-CON Livingston Health Campus Medilodge of Howell 2009-6458-CON	9/22/08	Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The three applicants are: (1) Trilogy Healthcare of Livingston, LLC, (2) Livingston Care Center, LLC and (3) MediLodge of Howell, Inc. (petitioner).	The parties agreed to stay this matter until resolution of Compare Group 95-0184. Since that matter is now resolved, the ALJ has set a pre-hearing conference for April 7, 2010.

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Macomb County - Compare Group # 950185 <u>INCLUDES</u>: FountainBleu-Shelby Township 2009-19036-CON Utica Health Campus 2009-19041-CON Medilodge of Richmond 2009-19039-CON Medilodge of Sterling Heights 2009-19040-CON Medilodge of Washington 2009-19042-CON Heartland Health Care Center – Macomb 2009-19038-CON Windemere Park Nursing Center 2009-19043-CON	4/30/09	Macomb County – Comparative Review of nursing home beds – Administrative Appeal. The seven applicants are: ,(1) Fountainbleu, LLC (petitioner) (2) HCR ManorCare Services, LLC (successful applicant) (3) MediLodge of Richmond, LLC (petitioner) (4) MediLodge of Sterling Heights, Inc. (petitioner) (5) Trilogy Healthcare of Macomb, LLC (successful applicant) (6) MediLodge of Washington, LLC (petitioner) and (7) VanDyke Partners, LLC (successful applicant).	On February 10, 2010, the Administrative Law Judge issued a 32-page Proposal for Decision to Grant the Department of Community Health's Motion for Summary Disposition (PFD). The ALJ found that DCH properly conducted the comparative review and that DCH properly determined that Fountainbleu and the Medilodge entities' CON applications did not demonstrate compliance with MCL 333.2225(1) by failing to comply with the applicable revised CON standards for nursing home beds. The appellants filed exceptions to the PFD and DCH filed responses to the exceptions. We are currently waiting for a final decision from the Director.

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Macomb County INCLUDES: Heartland Health Care Center – III	10/15/09	Macomb County – nursing home beds – Administrative Appeal. There was only one applicant, Heartland Health Center – Macomb III.	The parties agreed to stay this matter until resolution of Compare Group 95-0185.

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Case Name	**Date Opened**	**Case Description**	**Status**
Oakland Count y- Compare Group # 950177 INCLUDES: Woodward at Bloomfield Hills 2009-19212-CON McAuley Center 2009-19215-CON Waltonwood at Twelve Oaks – 3 2009-19214-CON Waltonwood at Main – 2 2009-19213-CON The Manor of Farmington Hills 2009-19044-CON Bloomfield Orchard Villa 2009-19136-CON	4/30/09	Oakland County – Comparative Review of nursing home beds – Administrative Appeal. The six applicants are: ,(1) Manor of Farmington Hills (petitioner), (2) Bloomfield Orchard Villa (petitioner), (3) Woodward at Bloomfield Hills Health Center (approved applicant), (4) Waltonwood at Main (approved applicant), (5) Waltonwood at Twelve Oaks (approved applicant, and (6) McAuley Center (approved applicant).	On February 19, 2010, the Administrative Law Judge issued a 24-page Proposal for Decision to Grant the Department of Community Health's Motion for Summary Disposition (PFD). The ALJ found that DCH properly conducted the comparative review and that DCH properly determined that the Manor of Farmington Hills' and Bloomfield Orchard Villa's CON applications did not demonstrate compliance with MCL 333.2225(1) by failing to comply with the applicable revised CON standards for nursing home beds. The appellants filed exceptions to the PFD and DCH filed responses to the exceptions. We are currently waiting for a final decision from the Director.

CERTIFICATE OF NEED LEGAL ACTION

(3/25/10)

Oakland County INCLUDES: West Winds Health Center	4/30/09	Oakland County – nursing home beds – Administrative Appeal. There was only one applicant, West Winds Health Center.	The parties agreed to stay this matter until resolution of Compare Group 95-0177.
Woodcare X (Caretel) v MDCH Genesee County Cir Docket No.: 08-89784 CZ	10/08/08	Complaint for Mandamus	Parties have stipulated to an order of dismissal which was submitted to the Court on 8/27/09. Order entered 9/24/09 and appealed. CA no 294480.
Woodcare X (Caretel) v MDCH Court of Claims Docket No.: 08-132-MK	12/03/08	Filed for damages and specific performance of a settlement agreement reached 20 years ago.	Court rescheduled trial to 11/10/09, then denied our motion based on government immunity. Appeal filed 10/27/09, and case stayed. No 294824; consolidated with 294480.
Woodcare X (Caretel) v MDCH	10/27/09	Appeal of Mandamus and Court of Claims.	Brief filed. In February, the Court denied a request to lift the automatic stay.
MDCH v Woodcare X (Caretel) and CMS U.S. District Court (Western)	08/27/09	Filed Complaint for Declaratory & Injunctive Relief	The Court dismissed the complaint on January 22, 2010, finding it lacked jurisdiction. DCH agreed with our recommendation not to appeal.

s: chd; assign control; special; CON Leg Action; report 11/23/09

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.

Attachment S

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2009												2010											
	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	•	•	• R F	•	•	•	•	• —	•	P •	• ▲ F			
Bone Marrow Transplantation (BMT) Services	• R	•	• R	•	•	▮	▮	▮	▮	▮	▮	• —	•	P •	• ▲ F									
Cardiac Catheterization Services															•	•	•	•	•	•	•	PH ▮	▮	▮
Computed Tomography (CT) Scanner Services										PH •	•	•	• R	•	•	•	▮	▮	▮	▮	▮	▮	▮	• —
Heart/Lung and Liver Transplantation Services	• R	•	•	▮	▮	▮	▮	▮	▮	▮	•	• —	•	P •	• ▲ F									
Hospital Beds and Addendum for HIV Infected Individuals																						PH		
Magnetic Resonance Imaging (MRI) Services	• R	•	•	•	•	• —	• P	•	• ▲ F R	•	•	• —	•	P •	• ▲ F									
Megavoltage Radiation Therapy (MRT) Services/Units																						PH		
Neonatal Intensive Care Services/Beds (NICU)										PH •	•	•	• R	•	• —					P •	• ▲ F			
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										PH •	•	•	• R	•	•	•	•	•						
Open Heart Surgery Services																						PH		
Positron Emission Tomography (PET) Scanner Services																						PH		
Surgical Services																						PH		
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units										PH •	•	•	• R	•	• R									
New Medical Technology Standing Committee	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M R
Administrative Rules	•	•	• R	•	•	• R	•	•	• R	•	•	• R	•	•	• R D									

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 Approval March 25, 2010

Updated March 16, 2010

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	2013
Bone Marrow Transplantation Services	November 13, 2008	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	June 4, 2004	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2011
Magnetic Resonance Imaging (MRI) Services	November 5, 2009	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2013
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

*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.