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

Thursday, June 10, 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 9:48 a.m.

A. Members Present:

Peter Ajluni, DO
Bradley Cory
James B. Falahee, Jr., JD, Vice-Chairperson
Edward B. Goldman, Chairperson
Marc Keshishian, MD
Brian Klott
Adam Miller
Michael A. Sandler, MD
Vicky Schroeder
Michael W. Young, DO

B. Members Absent:

Gay L. Landstrom

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
William Hart
Irma Lopez
Larry Horvath
Nick Lyon
Tania Rodriquez
Brenda Rogers
Rose Moye

II. Introductions

Chairperson Goldman welcomed everyone to the meeting and mentioned there would be an orientation for our new members after the meeting.

III. Bylaws

Mr. Potchen gave a brief overview of the amendment to Article X of the Bylaws which was presented and accepted at the March 25th meeting for final action at the June 10th meeting.

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to approve the amendment to Article X of the Bylaws. Motion carried.

IV. Review of Agenda

Motion by Commissioner Falahee, seconded by Commissioner Sandler, to amend and approve the agenda with the addition of Senator Cameron Brown to address the Commission regarding MRI. Motion Carried.

V. Declaration of Conflicts of Interests

None.

VI. Review of Minutes – March 25, 2010

Motion by Commissioner Sandler, seconded by Commissioner Falahee, to approve the minutes of March 25, 2010 with corrections to the second and third paragraphs and added a sixth paragraph under Election of Officers. Motion carried.

Correction/Re-write
XX. Election of Officers

Motion by Commissioner Ajluni, seconded by Commissioner Landstrom, to nominate and elect Commissioner Goldman as Chairperson of the Commission. Yes – 6, No – 1, Abstained -1. Motion Carried.

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

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

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.

Chairperson Goldman invited Commissioner Ajluni to participate in Executive meetings.

VII. Neonatal Intensive Care Services/Beds (NICU)

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

B. Public Comment:

None.

C. Commission Discussion:

None.

D. Commission Final Action:

Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the language (Attachment B) as provided and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Yes – 10, No – 0, Abstained – 1. Motion Carried.

VIII. Air Ambulance Services

A. Chairperson Goldman gave an update, and Ms. Rogers gave an overview informing the Commission that the Air Ambulance Standards had been tabled from Final Action at the Commission's September 18, 2007 meeting. (Attachment C)

Motion by Commissioner Ajluni, seconded by Commissioner Keshishian, to remove the tabled air ambulance standards for discussion and action at today's meeting. Yes – 10, No – 0, Abstained – 0. Motion Carried.

B. Public Comment:

Meg Tipton, Spectrum Health

C. Commission Discussion:

Discussion followed.

D. Commission Final Action:

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to accept the language as provided (Attachment C) and move forward to the JLC and Governor for the 45-day review period. Yes – 10, No – 0, Abstained – 0. Motion Carried.

IX. Bone Marrow Transplantation (BMT) Services – PPS Exemption

A. Carol Kristner, Barbara Ann Karmanos Cancer Institute, presented and gave an overview of the revised Section 4 excerpt from the BMT standards. (Attachment D)

B. Public Comment:

Carol Christner, Karmanos Cancer Center
Shawn Gailey, Ascension Health
Dennis McCafferty, Economic Alliance of Michigan

C. Commission Discussion:

Discussion followed.

D. Commission Proposed Action:

Motion by Commissioner Sandler, seconded by Commissioner Cory, to accept the revised Section 4 language of the BMT standards (Attachment D) and move forward for public hearing. Further, to have the Department report back to the Commission, within the next 6 months, regarding the possible removal of the PPS exemption requirement from the standards. Yes – 10, No – 0, Abstained – 0. Motion Carried.

X. Nursing Home and Hospital Long-Term Unit Beds and Addendum for Special Population Groups (NH-HLTCU)

A. Ms. Rogers gave an update, and Mr. Hart summarized the process leading to the development of the presented language. (Attachment E)

Motion by Commissioner Cory, seconded by Commissioner Miller, to refer back to the Department to discuss with interested parties and to bring back to the September Commission meeting for proposed action.

B. Public Comment:

Pat Anderson, Health Care Association of Michigan
Dennis McCafferty, Economic Alliance of Michigan
Sara Slocum, Michigan Long Term Care Ombudsman

C. Commission Discussion:

None.

D. Commission Action:

Vote on the motion: Yes – 10 No – 0, Abstained – 0. Motion Carried.

XI. Public Comment

Senator Cameron Brown on behalf of Hillsdale Community Health Center (Attachment F)

Recessed at 11:10 a.m. and reconvened at 11:20 p.m.

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

A. Ms. Lopez gave an overview of the Department's original report (Attachment G) that was provided to the Commission at the March 25 Commission meeting. A discussion group was held on April 28, 2010, and she provided an overview of the discussion summary (Attachment H). The discussion group's conclusion, excluding the Department, was that lithotripsy should continue to be regulated. The Department affirmed it's original position to deregulate this service.

B. Public Comment:

Sean Gehle, Ascension Health
Dennis McCafferty, Economic Alliance of Michigan
Karen Kippen, Henry Ford System
Monica Harrison, Oakwood
Penny Crissman, Crittenton Hospital
Jorgen Mattson, Great Lakes Lithotripsy

C. Commission Discussion:

Discussion followed.

D. Commission Proposed Action:

Motion by Commissioner Falahee, seconded by Commissioner Klott, to continue the UESWL standard and not to deregulate. Yes – 10, No – 0, Abstained – 0. Motion Carried.

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

Mr. Hart gave a brief staffing update.

A. Health Policy Section Update:

1. Ms. Lopez gave a brief overview on the Heart/Lung and Liver (HLL) Transplantation Services, definition of "initiate" or "implement." (Attachment I).

   The Commission had a discussion on HLL services and recommended that a revision of the standard is not necessary at this time.

2. Ms. Lopez gave a brief overview of the considerations for a draft SAC charge for Cardiac Catheterization Services. (Attachment J)

   Motion by Commission Sandler, seconded by Commissioner Ajluni, to delegate approval of the charge to the Chairperson and Vice-chairperson. Yes – 10, No – 0, Abstained – 0. Motion Carried

B. CON Evaluation Section Update:

Mr. Horvath gave an update on the CON Evaluation Section which included a slide presentation of the annual survey by Ms. Moore.

XVI. Legal Activity Report

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

XVII. Future Meeting Dates

September 23, 2010
December 15, 2010

XVIII. Public Comment

None.

XI. Review of Commission Work Plan

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

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to approve the Work Plan as presented. Yes –10, No – 0, Abstained – 0. Motion Carried.

Commissioner Falahee volunteered to take the lead to revising the Guiding Principles for the Commission.

XII. Adjournment

Motion by Commissioner Sandler, seconded by Commissioner Miller, to adjourn the meeting at 12:45 p.m. Motion Carried.

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

Date: May 17, 2010

TO: Irma Lopez

FROM: Brenda Rogers

RE: Summary of Public Hearing Comments on Neonatal Intensive Care Services/Beds (NICU) Standards and MDCH Policy Staff Analysis

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the NICU Standards at its March 25, 2010 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed NICU Standards on May 7, 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 one organization and is summarized as follows:

Mary Boyd, Mercy Health Partners:

Trinity Health would like a thorough review of the NICU standards with the establishment of a standard advisory committee (SAC). There is a pending consolidation of the Mercy/Hackley birth centers which will be located on Mercy Health Partners Hackley campus. They will be one of only two hospitals in the state with over 2,500 births and no NICU. The threshold to initiate is 2,000 live births which they will be able to meet. However, there is no unmet need in the planning area. In their testimony, they state "It is clear that there is an access problem for residents in Muskegon County and surrounding areas. Access to NICU services only in Grand Rapids restricts the ability of families to be part of the care team for their ill newborns."

Staff Analysis and Recommendations

As stated in the 1/20/10 Department recommendation and analysis, the bed need methodology takes into account and compensates for the decrease in live births by lowering the bed need. Pursuant to the January 4, 2010 Bed Inventory, all

planning areas are overbedded; HSA 3 is currently overbedded by 8. It is recommended that no action be taken on this issue.

The Department supports the CON Commission's March 25, 2010 proposed action, as written.

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

CERTIFICATE OF NEED (CON)REVIEW STANDARDS FOR AIR AMBULANCE SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve air ambulance services.

(2) Air ambulance 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 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 8, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 7, IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.2215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

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

(A) "ACQUISITION OF AN EXISTING AIR AMBULANCE SERVICE" MEANS OBTAINING POSSESSION AND CONTROL OF AN EXISTING AIR AMBULANCE SERVICE BY CONTRACT, OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT.

(~~a~~B) "Advanced life support services" means patient care that may include any care a paramedic is qualified to provide by paramedic education that meets the educational requirements established by the Department under Section 20912 of the Code, being Section 333.20912 of the Michigan Compiled Laws, or is authorized to provide by the protocols established by the local medical control authority under Section 20919 of the Code, being Section 333.20919 of the Michigan Compiled Laws, for a paramedic.

(~~b~~C) "Advanced life support intercept~~,~~" ~~for purposes of these standards,~~ means the use of an air ambulance to provide advanced life support services to a patient at the scene of an emergency that does not involve the transport of that patient by air.

(~~c~~D) "Air ambulance~~,~~" ~~for purposes of these standards,~~ means a rotary wing aircraft that is capable of providing treatment or transportation of a patient at or from the scene of an emergency. An air ambulance may also be used for the inter-facility transport of a patient requiring AT MINIMUM advanced life support~~., critical care support or specialty care support services.~~ The term does not include ~~either a fixed wing aircraft; or~~ an air ambulance licensed in a state other than Michigan that does not transport patients from the scene of an emergency in Michigan, except pursuant to mutual aid agreements, and which is not required to be licensed as an air ambulance under Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

(~~d~~E) "Air ambulance service" means PROVIDING AT LEAST ADVANCED LIFE SUPPORT SERVICES UTILIZING ~~the provision of emergency medical and air medical services by means of 1 or more~~ AN air ambulance(s) that operateS in conjunction with a base ~~of operations~~ HOSPITAL(S). ~~The service shall be capable of providing at least advanced life support services but may include the provision of critical care or specialty care support services.~~ Other functions of the service may include ~~advanced~~

~~life support intercepts,~~ searchES, ~~and rescue, and~~ emergency transportation of drugs, organs, medical supplies, equipment or personnel. An air ambulance service may operate a~~n additional~~ BACK-UP air ambulance WHEN THE PRIMARY AIR AMBULANCE(S) IS NOT AVAILABLE OR FOR ~~for the purpose of~~ a designated event with ~~the~~ prior notification AND APPROVAL ~~and approval of~~ FROM the local medical control authority. ~~and the Department Division of Emergency Medical Services.~~

~~(e) "Air medical personnel" means the patient care staff involved in the provision of an air ambulance service and shall include at least 2 members, one of which shall be a paramedic licensed in Michigan.~~

~~(f) "Air medical service" means a service that provides air transportation to patients requiring medical care and has provisions for at least all of the following components:~~

~~(i) written policies and procedures specifying the mission statement and levels of patient care to be provided. The level of patient care provided shall be commensurate with the education and experience of the air medical team and the capabilities of the base of operations.~~

~~(ii) written patient care protocols including provisions for continuity of care;~~

~~(iii) written policies and procedures that define the roles and responsibilities of all air medical team members;~~

~~(iv) written operational policies and procedures addressing staff minimum licensure and/or certification requirements, work schedules and safety requirements;~~

~~(v) written policies and procedures addressing the appropriate use of air ambulance services;~~

~~(vi) a written communicable disease and infection control program;~~

~~(vii) a written plan for dealing with situations involving hazardous materials;~~

~~(viii) a planned and structured program for initial and continuing education and training, including didactic, clinical and in-flight, for all scheduled air medical team members appropriate for the respective duties and responsibilities;~~

~~(ix) written policies and procedures addressing the integration of the air medical service with public safety agencies governing the primary service area including but not limited to the federal aviation administration, medical control authorities, ground emergency vehicles and disaster planning;~~

~~(x) written policies and procedures governing the aircraft equipment and configuration, flight operations and communications;~~

~~(xi) a quality management program; and~~

~~(xii) a community education program.~~

~~(g) "Air medical team" means the personnel involved in the provision of an air ambulance service including the medical, aviation, maintenance, administrative and communication functions.~~

~~(h) "Acquisition of an existing air ambulance service" means obtaining possession or control of an existing air ambulance service by contract, ownership, lease or other comparable arrangement.~~

(~~i~~F) "Back-up air ambulance" means an air ambulance that is used to provide air ambulance services when the primary air ambulance is not available TO PROVIDE AIR AMBULANCE SERVICES~~for patient transports~~. A back-up air ambulance shall not be operated at the same time as the primary aircraft for the provision of air ambulance services EXCEPT FOR A DESIGNATED EVENT.

(~~j~~G) "Base ~~of operations~~ HOSPITAL(S)" means the hospital or hospitals designated by the applicant in the CON application as the location(s) to which the majority of patient transports will be completed.

(H) "BASE OF OPERATIONS" MEANS THE SITE OR SITES AT WHICH THE AIR AMBULANCE(S) AND CREW ARE LOCATED FOR THE AIR AMBULANCE SERVICE.

(~~k~~I) "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.

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

~~(m) "Critical care support" means care provided directly by a Michigan licensed physician or registered nurse as part of the air medical personnel.~~

(~~n~~K) "Department" means the Michigan Department of Community Health (MDCH).

~~(o) "Department inventory of air ambulances" or "Department Inventory" means the list, maintained by the Department on a continuous basis, of:~~

~~(i) air ambulances operating pursuant to a valid CON issued under Part 222 or former Part 221 of~~

~~the Code;~~

~~(ii) air ambulances licensed and operating in Michigan for which the operation of the air ambulance did not require a CON; and~~

~~(iii) air ambulances which are not yet operational but have a valid CON issued under Part 222 or former Part 221 of the Code.~~

~~The inventory shall not include back-up air ambulances.~~

(~~p~~L) "Designated event" means a temporary event, such as an air show, of no more than seven (7) days in duration that requires the full-time on-site availability of an air ambulance.

(~~q~~M) "Emergency" means a condition or situation in which an individual declares a need for immediate medical attention for any individual, or where that need is declared by emergency medical services personnel or a public safety official, PURSUANT TO MCL 333.20904.

(N) "EXISTING AIR AMBULANCE" MEANS AN OPERATIONAL AIR AMBULANCE ON THE DATE WHICH AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(~~r~~O) "Existing air ambulance service" means an OPERATIONAL air ambulance service OR AN AIR AMBULANCE SERVICE APPROVED, BUT NOT YET OPERATIONAL ~~listed on the Department inventory of air ambulances~~ on the date ~~on~~ which an application is submitted to the Department.

(~~s~~P) "Expand an air ambulance service" means increasing the number of air ambulances operated by an existing air ambulance service ~~from the same base of operations~~.

~~(t) "Fixed wing aircraft," for purposes of these standards, means an aircraft licensed under Part 209 of the Code, being Section 333.20901 et seq. of the Michigan Compiled Laws, that is not a rotary wing aircraft and is capable of providing patient care according to orders issued by a patient's physician.~~

(~~u~~Q) "Health facility" means a health facility or agency as defined in Section 20106 of the Code, being Section 333.20106 of the Michigan Compiled Laws.

(~~v~~R) "Hospital" means a health facility licensed under Part 215 of the Code.

~~(w) "Implementation plan" means a plan that documents how an applicant will implement and operate a proposed air ambulance service or an existing air ambulance service that is proposed to be acquired. The plan shall include documentation of at least each of the components of an air medical service including how the air ambulance service will be integrated with local medical control authority(s).~~

(~~x~~S) "Initiate an air ambulance service" means begin operation of an air ambulance service from a base of operations that does not ~~offer~~ PROVIDE air ambulance services in compliance with Part 222 of the Code and is not listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department. The term does not include the renewal of a lease.

(~~y~~T) "Inter-facility transport~~,~~" ~~for purposes of these standards,~~ means the transport of a patient between health facilities using an air ambulance.

(~~Z~~U) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to1396v.

(~~AA~~V) "Medical control authority" means an organization designated by the Department under Section 20910(1)(~~kg~~) TO PROVIDE MEDICAL CONTROL, PURSUANT TO MCL 333.20906.~~of the Code, being Section 333.20910(1)(k) of the Michigan Compiled Laws.~~

(~~BB~~W) "Monitored bed" means a licensed hospital bed that has, at a minimum, the capability of electronically monitoring in real time a patient's cardiac activity.

(~~CC~~X) "Mutual aid~~,~~" ~~for purposes of these standards,~~ means a written agreement between 2 or more air ambulance services for the provision of emergency medical services when an air ambulance service is unable to respond to a request for a pre-hospital transport.

(Y) "ORGAN TRANSPORT" MEANS THE USE OF AN AIR AMBULANCE TO TRANSPORT AN ORGAN(S) AND SURGICAL TRANSPLANT TEAM BETWEEN HOSPITALS FOR TRANSPLANTATION PURPOSES OCCURRING IN MICHIGAN.

~~(DD) "Offer" means to make patient transports.~~

(~~EE~~Z) "Patient transport~~,~~" ~~for purposes of these standards,~~ means the use of an air ambulance TO PROVIDE AN ADVANCED LIFE SUPPORT INTERCEPT, A PRE-HOSPITAL TRANSPORT OR AN INTER-FACILITY TRANSPORT OCCURRING IN MICHIGAN. ~~for the transport and treatment of a single patient for an inter-facility transport or a pre-hospital transport. The term does not include use of an air~~

~~ambulance that does not involve the transport of a patient.~~

(~~FF~~AA) "Pre-hospital transport" means the use of an air ambulance to provide transportation and advanced life support services to a patient from the scene of an emergency to a hospital.

~~(GG) "Primary service area" means the geographic service area that is or will be authorized by an air ambulance service's license and encompasses the area(s) to which the air ambulance service will primarily make pre-hospital transports.~~

~~(HH) "Quality management program" means a planned and structured program to evaluate the appropriateness, necessity, and effectiveness of an air ambulance service.~~

~~(II) "Receiving hospital" means a hospital to which an air ambulance will transport patients.~~

~~(JJ) "Renewal of a lease" means extending the effective period of a lease for a helicopter for an existing air ambulance service that does not involve either the replacement of a helicopter or a change in the parties to the lease.~~

(~~KK~~BB) "Replace an air ambulance" means ~~either:~~ an equipment change which results in an air ambulance service operating an air ambulance, ~~other than a back-up air ambulance,~~ with a different aircraft manufacturer's serial number, OTHER THAN A BACK-UP AIR AMBULANCE., ~~and an applicant operating the same number of air ambulances before and after project completion at the same base of operations; or the renewal of a lease~~.

(~~LL~~CC) "Rotary wing aircraft" means a helicopter.

~~(MM) "Secondary service area" means an area in which an air ambulance service will make inter-facility transports or pre-hospital transports, or may operate pursuant to mutual aid agreements.~~

~~(NN) "Specialty care support" means care provided by one or more professionals who can be added to or substituted for one of the regularly scheduled air medical personnel for the provision of specialty services.~~

(2) The definitions of Part 209 and 222 shall apply to these standards.

Section 3. Requirements for approval ~~for applicants proposing~~ to initiate an air ambulance service

Sec. 3. ~~(1)~~ An applicant proposing to initiate an air ambulance service shall: ~~submit an implementation plan in a CON application when it is submitted to the Department.~~

(1) OPERATE ONLY ONE (1) AIR AMBULANCE.

(2) IDENTIFY THE BASE HOSPITAL(S) OF THE PROPOSED AIR AMBULANCE SERVICE.

(3) IDENTIFY THE BASE OF OPERATIONS OF THE PROPOSED AIR AMBULANCE SERVICE.

(4) PROVIDE A LETTER OF SUPPORT FROM THE MEDICAL CONTROL AUTHORITY FOR THE BASE OF OPERATIONS INDICATING THAT THE APPLICANT'S PROPOSED PROTOCOLS COMPLY WITH THE REQUIREMENTS OF THE MEDICAL CONTROL AUTHORITY.

~~(2) An applicant proposing to initiate an air ambulance service shall demonstrate all of the following:~~

(~~a~~5) ~~An applicant shall project~~ PROJECT, in accordance with the methodology ~~set forth~~ in Section 9, that at least 275 patient transports will be made ~~in months 7 through 18~~ IN THE SECOND 12 MONTHS after beginning operation~~, and annually thereafter~~.

~~(b) At least 80% of the projected total number of patient transports will result in an admission to a monitored bed in a hospital or involve the transport of a patient who expires prior to admission to a hospital.~~

~~(c) An application proposes to operate only 1 rotary wing aircraft.~~

(~~d~~6) ~~An applicant shall demonstrate, in its application on the date it is submitted to the Department,~~ DEMONSTRATE that all existing air ambulance services with a base of operations within a 75-mile radius

of the base of operations of the proposed air ambulance service have been notified of ~~an~~ THE applicant's intent to initiate an air ambulance service~~. An applicant shall demonstrate~~, by means of ~~the date on a~~ certified mail return receipt, DATED BEFORE THE DEEMED COMPLETE DATE OF THE APPLICATION~~, that such notice was given to each service at least 45 days prior to the date an application is submitted to the Department~~.

Section 4. Requirements for approval ~~for applicants proposing~~ to expand an air ambulance service

Sec. 4. An applicant proposing to expand an air ambulance service shall: ~~demonstrate each of the following:~~

(~~a~~1) ~~An average of at least 600 patient transports for each existing air ambulance was made during~~ DEMONSTRATE THAT IN the most recent 12-month period for which verifiable data are available to the Department, ~~.~~ THE AIR AMBULANCE SERVICE MET ONE (1) OF THE FOLLOWING:

(A) 600 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE EXPANDING TO TWO (2) AIR AMBULANCES, OF WHICH 275 MUST BE PATIENT TRANSPORTS;

(B) 1,200 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE EXPANDING TO THREE (3) AIR AMBULANCES, OF WHICH 550 MUST BE PATIENT TRANSPORTS;

(C) 1,800 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE EXPANDING TO FOUR (4) AIR AMBULANCES, OF WHICH 825 MUST BE PATIENT TRANSPORTS.

~~(b) An applicant shall project, in accordance with the methodology set forth in Section 9, that the number of patient transports to be made in the months 7 through 18 after beginning operation of an additional air ambulance, and annually thereafter, is equal to or greater than 600 multiplied by the existing number of air ambulances plus 200. For example, an air ambulance service with 1 air ambulance shall project that at least 800 patients transports (600 x 1 + 200 = 800) will be made in months 7 through 18 after beginning operation of the additional air ambulance.~~

~~(c) An applicant proposes the addition of 1 air ambulance.~~

~~(d) An applicant, approved under these standards, shall demonstrate that, at the time an application is submitted to the Department to expand an air ambulance service, an applicant is in compliance with each of the project delivery requirements set forth in Section 8 of these standards, if such application is filed subsequent to 24 months after the date a CON is approved pursuant to these standards.~~

(2) IDENTIFY THE EXISTING BASE OF OPERATIONS OF THE AIR AMBULANCE SERVICE.

(3) IDENTIFY ANY PROPOSED BASE OF OPERATIONS AND DEMONSTRATE THAT THE PROPOSED BASE OF OPERATIONS IS WITHIN THE SAME MEDICAL CONTROL AUTHORITY AS THE EXISTING BASE OF OPERATIONS.

(4) IDENTIFY THE EXISTING AND PROPOSED BASE HOSPITAL(S) OF THE AIR AMBULANCE SERVICE.

Section 5. Requirements for approval ~~for applicants proposing~~ to replace an air ambulance

Sec. 5. An applicant proposing to replace an existing air ambulance shall: ~~demonstrate either of the following, as applicable:~~

(~~a~~1) ~~An air ambulance service that operates 1 air ambulance shall demonstrate that at least 275~~

~~patient transports were made in~~ DEMONSTRATE THAT IN the most recent 12-month period for which verifiable data are available to the Department, THE AIR AMBULANCE SERVICE MET ONE (1) OF THE FOLLOWING:~~.~~

(A) 275 PATIENT TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH ONE (1) AIR AMBULANCE;

(B) 600 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH TWO (2) AIR AMBULANCES, OF WHICH 550 MUST BE PATIENT TRANSPORTS;

(C) 1,200 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH THREE (3) AIR AMBULANCES, OF WHICH 825 MUST BE PATIENT TRANSPORTS;

(D) 1,800 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH FOUR (4) AIR AMBULANCES, OF WHICH 1,100 MUST BE PATIENT TRANSPORTS.

~~(b) An air ambulance service that operates 2 or more air ambulances shall demonstrate that the number of patient transports made in the most recent 12-month period for which verifiable data are available to the Department was equal to or greater than the number of patient transports required in Section 4(b) applicable to the number of air ambulances operated by an applicant.~~

(~~c~~2) ~~An applicant proposing to replace an air ambulance that does not involve a renewal of a lease shall demonstrate that the~~ DEMONSTRATE THAT THE existing ~~helicopter~~ AIR AMBULANCE to be replaced is fully depreciated according to generally accepted accounting principles, or that the replacement ~~helicopter~~ AIR AMBULANCE offers significant technological improvements which enhance safety or quality of care, increases efficiency, or reduces operating costs.

~~(d) An applicant, approved under these standards, shall demonstrate that, at the time an application to replace an air ambulance is submitted to the Department, an applicant is in compliance with each of the project delivery requirements set forth in Section 8 of these standards, if such application is filed subsequent to 24 months after the date a CON is approved pursuant to these standards.~~

(3) IDENTIFY THE EXISTING BASE OF OPERATIONS OF THE AIR AMBULANCE SERVICE.

(4) IDENTIFY THE EXISTING BASE HOSPITAL(S) OF THE AIR AMBULANCE SERVICE.

(5) ASSERT THAT THE AIR AMBULANCE TO BE REPLACED SHALL BE REMOVED FROM OPERATION AT THE APPLICANT'S AIR AMBULANCE SERVICE OR DESIGNATED AS A BACK-UP AIR AMBULANCE.

Section 6. Requirements for approval ~~for applicants proposing~~ to acquire an existing air ambulance service

Sec. 6. An applicant proposing to acquire an existing air ambulance service shall: ~~demonstrate that it meets all of the following~~:

~~(a) The project is limited solely to the acquisition of an existing air ambulance service.~~

~~(b) The project will not result in an increase in the number of air ambulances listed on the Department inventory of air ambulances at the base of operations of the air ambulance service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4, as applicable.~~

~~(c) The project will not result in the replacement of the air ambulance(s) operated by the air ambulance service to be acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 5, as applicable.~~

(~~d~~1) ~~all air ambulances at the base of operations to be acquired are listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department and the acquisition shall not result in a change in the base of operations.~~ DEMONSTRATE THAT IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT, THE AIR AMBULANCE SERVICE MET ONE (1) OF THE FOLLOWING:

(A) 275 PATIENT TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH ONE (1) AIR

AMBULANCE;
(B) 600 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH TWO (2) AIR AMBULANCES, OF WHICH 550 MUST BE PATIENT TRANSPORTS;
(C) 1,200 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH THREE (3) AIR AMBULANCES, OF WHICH 825 MUST BE PATIENT TRANSPORTS;
(D) 1,800 PATIENT TRANSPORTS AND ORGAN TRANSPORTS FOR AN AIR AMBULANCE SERVICE WITH FOUR (4) AIR AMBULANCES, OF WHICH 1,100 MUST BE PATIENT TRANSPORTS.

~~(e) An applicant agrees to operate the air ambulance service in accordance with all applicable project delivery requirements set forth in Section 8 of these standards.~~
~~(f) An applicant shall submit an implementation plan in the CON application on the date on which it is submitted to the Department.~~

(2) IDENTIFY THE EXISTING BASE OF OPERATIONS OF THE AIR AMBULANCE SERVICE.

(3) IDENTIFY ANY PROPOSED BASE OF OPERATIONS AND DEMONSTRATE THAT THE PROPOSED BASE OF OPERATIONS IS WITHIN THE SAME MEDICAL CONTROL AUTHORITY AS THE EXISTING BASE OF OPERATIONS.

(4) IDENTIFY THE EXISTING AND PROPOSED BASE HOSPITAL(S) OF THE AIR AMBULANCE SERVICE.

(5) PROVIDE A LETTER OF SUPPORT FROM THE MEDICAL CONTROL AUTHORITY FOR THE BASE OF OPERATIONS INDICATING THAT THE APPLICANT'S PROPOSED PROTOCOLS COMPLY WITH THE REQUIREMENTS OF THE MEDICAL CONTROL AUTHORITY.

Section 7. Requirements for approval ~~--~~ FOR all applicants

Sec. 7. ~~(1) An applicant shall identify the primary and secondary service areas in which the existing or proposed air ambulance service will or does operate.~~
~~(2) An applicant shall identify the base of operations of the existing or proposed air ambulance service in its application.~~
~~(3)~~ 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. ~~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.~~

Section 8. Project delivery requirements--terms of approval for all applicants

Sec. 8. (1) An applicant shall agree that, if approved, the services provided by the air ambulance service shall be delivered in compliance with the following terms of CON approval:
(a) Compliance with these standards.
(b) Compliance with applicable state and federal safety, operating, and licensure standards.
(c) COMPLIANCE WITH ~~An approved air ambulance service shall operate in accordance with~~ applicable local medical control authority protocols for scene responses by air ambulances.
(D) AN AVERAGE OF 275 PATIENT TRANSPORTS ANNUALLY FOR EACH EXISTING AIR AMBULANCE.
(~~d~~E) Compliance with EITHER OF the following quality assurance standards:
~~(i) An approved air ambulance shall be operating at the applicable required volumes within the~~

~~time periods specified in these standards, and annually thereafter.~~

(~~ii~~I) THE APPLICANT SHALL BE ~~An applicant shall operate an air medical service. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of meeting this requirement if an applicant submits evidence that an air ambulance service is~~ accredited as an air AMBULANCE ~~medical~~ service by the Commission on the Accreditation of ~~Air~~ Medical TRANSPORT SYSTEMS ~~Services~~(CAMTS) within 2 years of beginning operation; OR ~~of an air ambulance service approved under these standards~~

(II) THE APPLICANT SHALL MAINTAIN THE FOLLOWING: ~~. However, an applicant may submit and the Department may accept other evidence that an applicant operates an air medical service.~~

(A) WRITTEN POLICIES AND PROCEDURES SPECIFYING THE LEVELS OF PATIENT CARE TO BE PROVIDED. THE LEVEL OF PATIENT CARE PROVIDED SHALL BE COMMENSURATE WITH THE EDUCATION AND EXPERIENCE OF THE STAFF AND THE CAPABILITIES OF THE BASE HOSPITALS.

(B) WRITTEN PATIENT CARE PROTOCOLS INCLUDING PROVISIONS FOR CONTINUITY OF CARE;

(C) WRITTEN POLICIES AND PROCEDURES THAT DEFINE THE ROLES AND RESPONSIBILITIES OF ALL STAFF MEMBERS;

(D) WRITTEN POLICIES AND PROCEDURES ADDRESSING THE APPROPRIATE USE OF AIR AMBULANCE SERVICES;

(E) A WRITTEN COMMUNICABLE DISEASE AND INFECTION CONTROL PROGRAM;

(F) A WRITTEN PLAN FOR DEALING WITH SITUATIONS INVOLVING HAZARDOUS MATERIALS;

(G) A PLANNED AND STRUCTURED PROGRAM FOR INITIAL AND CONTINUING EDUCATION AND TRAINING, INCLUDING DIDACTIC, CLINICAL AND IN-FLIGHT, FOR ALL SCHEDULED STAFF MEMBERS APPROPRIATE FOR THE RESPECTIVE DUTIES AND RESPONSIBILITIES;

(H) WRITTEN POLICIES AND PROCEDURES ADDRESSING THE INTEGRATION OF THE AIR AMBULANCE SERVICE WITH PUBLIC SAFETY AGENCIES GOVERNING THE BASE HOSPITALS INCLUDING BUT NOT LIMITED TO THE FEDERAL AVIATION ADMINISTRATION, MEDICAL CONTROL AUTHORITIES, GROUND EMERGENCY VEHICLES AND DISASTER PLANNING;

(I) A QUALITY MANAGEMENT PROGRAM;

(J) A CLINICAL DATA BASE FOR UTILIZATION REVIEW AND QUALITY ASSURANCE PURPOSES; AND

(K) PROCEDURES TO SCREEN PATIENTS TO ASSURE APPROPRIATE UTILIZATION OF THE AIR AMBULANCE SERVICE.

(~~iii~~) ~~An applicant shall:~~

~~(A) establish an air medical team;~~

~~(B) develop a clinical data base for utilization review and quality assurance purposes; and~~

~~(C) screen patients to assure appropriate utilization of the air ambulance service.~~

~~(iv) At a minimum, an air medical team shall include the following personnel, employed directly by the applicant or on a contractual basis, who shall be appropriately trained and licensed:~~

~~(A) an air medical service director whose responsibilities shall include assuring that all patients receive services appropriate for their needs;~~

~~(B) a medical director of the air medical service who shall be a physician licensed in Michigan and shall have appropriate training and familiarity with the appropriate use of air ambulance services;~~

~~(C) communication personnel;~~

~~(D) appropriately trained patient care personnel including but not limited to: physicians, registered nurses, emergency medical technicians, and paramedics;~~

~~(E) a clinical care supervisor;~~

~~(F) flight operations and aviation personnel;~~

~~(G) maintenance personnel; and~~

~~(H) on all pre-hospital transports, a paramedic licensed in Michigan.~~

~~(v) An applicant shall maintain an individual record of service maintenance on each air ambulance~~

~~operated by the approved service.~~

(~~vi~~F) ~~All approved air ambulances shall be~~ COMPLIANCE WITH STAFFING AND ~~equipped, at a minimum, with the~~ essential equipment as required by Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

~~(e) Compliance with the following requirements:~~

(~~i~~G) ~~An applicant shall respond~~COMPLIANCE WITH ~~, or ensure a response, to~~ all appropriate requests for services for ~~all~~ pre-hospital transports ~~within its primary service area~~.

(~~ii~~H) ~~An applicant, to assure~~ ASSURANCE that an air ambulance service will be utilized by all segments of the Michigan population, shall:

(~~A~~I) not deny air ambulance services to any individual based on ability to pay or source of payment;

(~~B~~II) provide air ambulance services to any individual based on the clinical indications of need for the service; and

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

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

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

~~(iv) An air ambulance to be replaced shall be removed from service.~~

(~~v~~J) ~~The applicant shall provide~~ PROVISION OF NOTICE TO the Department with a notice stating the date the new, additional, or replacement air ambulance, is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

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

~~(2) The operation of and referral of patients to an air ambulance service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

(~~3~~2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~ AGREED TO BY the applicant or its authorized agent.

Section 9. Methodology for ~~computing projected~~ PROJECTING patient transports

Sec. 9. An applicant required to project patient transports shall compute projected patient transports AS FOLLOWS: ~~in accordance with subsection (1) or (2), as applicable. In computing projected patient transports, an applicant shall consider weather and maintenance and training requirements on the ability to transport patients by air ambulance.~~

~~(1) An applicant proposing to initiate an air ambulance service shall:~~

(~~a~~1) Identify the BASE ~~receiving~~ hospital(S) ~~or hospitals~~ to which patient transports will be completed by the proposed air ambulance service.

(~~b~~2) IN ORDER TO INCLUDE DATA FROM ANY HOSPITAL, AN APPLICANT SHALL DOCUMENT IN THE APPLICATION EACH HOSPITAL'S INTENT TO UTILIZE THE PROPOSED AIR AMBULANCE SERVICE. For each hospital ~~in the proposed primary and secondary service areas~~ from which patients will be transported to ~~the receiving~~ A BASE hospital(s) ~~identified in subsection (a),~~ document each of the following:

(~~i~~A) The number of patients that were transferred to each BASE ~~receiving~~ hospital and either

admitted to a monitored bed or expired prior to admission during the most recent 12-month period preceding the date on which an application is submitted to the Department. ~~In order to include data from any hospital, an applicant shall document in the application each hospital's intent to utilize the proposed air ambulance service.~~

(~~ii~~B) The number of patients identified in subdivision (~~i~~A) that were transferred by ground transportation.

(~~iii~~C) The number of patients identified in subdivision (~~ii~~B) for which air transport would have been appropriate~~.~~ AND FOR WHICH AN EXISTING AIR AMBULANCE SERVICE WITHIN A 75-MILE RADIUS WAS UNAVAILABLE FOR REASONS OTHER THAN WEATHER.

(~~c~~3) An applicant shall document the number of patients transferred from the scene of an emergency by ground transport to the ~~receiving~~ BASE hospital(s) FOR WHICH AIR TRANSPORT WOULD HAVE BEEN APPROPRIATE AND FOR WHICH AN EXISTING AIR AMBULANCE SERVICE WITHIN A 75-MILE RADIUS WAS UNAVAILABLE FOR REASONS OTHER THAN WEATHER AND THE PATIENTS WERE EITHER ADMITTED TO A MONITORED BED OR EXPIRED PRIOR TO ADMISSION during the most recent 12-month period preceding the date on which an application is submitted to the Department ~~for which air transport would have been appropriate~~.

(~~d~~4) The projected number of patient transports shall be the sum of the results of subsections (~~b~~2)(~~iii~~C) and (~~c~~3).

~~(2) An applicant proposing to expand an existing air ambulance service shall:~~

~~(a) Document the actual number of patient transports made during the most recent 12-month period preceding the date on which an application is submitted to the Department.~~

~~(b) If the actual number of patient transports identified in subsection (a) is less than the number required to be projected pursuant to Section 4 of these standards, document the number of requests for patient transport that were denied during the most recent 12-month period preceding the date on which an application is submitted to the Department due to the unavailability of an existing air ambulance(s) for reasons other than weather.~~

~~(c) If the sum of the results of subsections (a) and (b) is less than the number of patient transports required to be projected pursuant to Section 4 of these standards, the additional number of projected patient transports necessary to demonstrate compliance with the minimum volume required by Section 4 of these standards shall be computed in accordance with subsection (1).~~

~~(d) The projected number of patient transports shall be the sum of the results of subsections (a), (b) and (c), as applicable.~~

~~**Section 10. Department Inventory of Air Ambulances**~~

~~Sec. 10. Appendix A sets forth the air ambulances listed on the Department Inventory of Air Ambulances as of the effective date of these standards. Modification to Appendix A shall be made by the Department pursuant to decisions on CON applications and Certificates of Need.~~

Section ~~11~~10. Effect on Prior CON Review Standards; Comparative reviews

Sec. ~~11~~10. (1) These CON review standards supersede and replace the CON Review Standards for Air Ambulance Services approved by the CON Commission on ~~April 19, 1995~~ MARCH 9, 2004 and effective on ~~June 9, 1995~~ JUNE 4, 2004.

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

~~APPENDIX A~~

~~DEPARTMENT INVENTORY OF AIR AMBULANCES~~

~~Air Ambulance Service City (County)~~	~~Number of Air Ambulances*~~	~~Base of Operations~~
~~Butterworth AeroMed Grand Rapids (Kent)~~	~~1~~	~~Butterworth Hospital~~
~~Flight Care Saginaw (Saginaw)~~	~~1~~	~~St. Mary's Med Ctr~~
~~LifeNet Saginaw, (Saginaw)~~	~~1~~	~~Covenant Medical Center – Cooper~~
~~Midwest MEDFLIGHT Ypsilanti (Washtenaw)~~	~~1~~	~~St. Jos. Mercy Hosp--Ann Arbor~~ ~~Children's Hosp of MI~~ ~~Detroit Receiving Hospital and University Health Center~~ ~~Hutzel Hospital~~ ~~Harper Hospital~~
~~North Flight Traverse City (Gr. Traverse)~~	~~1~~	~~Munson Med Ctr~~
~~Promedica Continuing Care Services Corp. Toledo, OH~~	~~1~~	~~Toledo Hospital~~
~~St. Vincent Med Ctr Toledo, OH~~	~~2~~	~~St. Vincent Med Ctr~~
~~Survival Flight Ann Arbor (Washtenaw)~~	~~2~~	~~University of Michigan Hospitals~~
~~West Michigan Air Care Kalamazoo (Kalamazoo)~~	~~1~~	~~Borgess Med Ctr~~ ~~Bronson Meth Hosp~~

~~*Does not include back-up air ambulances~~

EXCERPT FROM
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION (BMT) SERVICES

Section 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, OR AN APPLICANT PREVIOUSLY APPROVED UNDER 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 OR SUCH LATER DATE AS THE DEPARTMENT MAY HAVE PREVIOUSLY APPROVED, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the 113TH ~~next~~ United States Congress ~~in session after the effective date of these standards~~. Extension of the deadline UNTIL THE END OF THE 113TH CONGRESS shall require THE FILING OF A CON APPLICATION UNDER THIS SECTION THAT PROVIDES demonstration by the applicant, to the satisfaction of the Department, that THE APPLICANT IS CONTINUING TO PURSUE ~~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 extensionS, then the Department may expire the CON granted pursuant to this SUBsection ~~and will not be subject to further applications for acquisition~~. However, prior to the DEPARTMENT ~~final deadline for the expiration of~~ EXPIRING the CON, the ~~prior~~ ORIGINAL 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 subsectionS (c) AND (G).

2. Applicants proposing to acquire an existing BMT service under this section shall not be subject to comparative review.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

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

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

~~(4) The Department shall use Section 11 of these standards, 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(2) of these standards, as applicable, in applying Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws.~~

Section 2. Definitions

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

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

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

(c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application.

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

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

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

(g) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department's Bureau of Health Systems.

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

(i) "Converted space" means existing space in a health facility that is not currently licensed as part of the nursing home/HLTCU and is proposed to be licensed as nursing home or HLTCU space. An example is proposing to license home for the aged space as nursing home space.

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

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

(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

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

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

(o) "Licensed only facility" means a licensed nursing home that is not certified for Medicare or Medicaid.

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

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

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

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

(t) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.

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

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

~~(w)~~ "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical

treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term applies to the licensee only and not the real property owner if different than the licensee.

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

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

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

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

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

(~~cc~~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.

(~~dd~~AA) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different licensed site within the planning area.

(~~ee~~BB) "Renewal of lease" means execution of a lease between the licensee and a real property owner in which the total lease costs exceed the capital expenditure threshold.

(~~ff~~CC) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(~~gg~~DD) "Replacement zone" means a proposed licensed site that is,

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

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

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

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

(~~hh~~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 C.

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

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

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

Section 3. Determination of needed nursing home bed supply

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

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

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

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

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

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

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

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

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

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

Section 4. Bed need

Sec. 4. (1) The bed need numbers shown in Appendix B and incorporated as part of these standards shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

(2) The Department shall apply the bed need methodology in Section 3 on a biennial basis.

(3) The base year and the planning year that shall be utilized in applying the methodology pursuant to subsection (2) shall be set according to the most recent data available to the Department.

(4) The effective date of the bed need numbers shall be established by the Commission.

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

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

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

Sec. 5. (1) The base year shall be modified based on data obtained from the Department and presented to the Commission. The Department shall calculate use rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates based on 2006 information, or the most recent base year information available biennially after 2006, to the CON Commission.

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

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

Section 6. Requirements for approval to increase beds in a planning area

Sec. 6. An applicant proposing to increase the number of nursing home beds in a planning area must meet the following as applicable:

(1) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in Appendix B, unless one of the following is met:

(i) An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area set forth in Appendix B, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

(ii) An exception to the number of beds may be approved, if the applicant facility has experienced an average occupancy rate of 97% for 12 quarters based on the Department's "Staffing/Bed Utilization Ratios Report." The number of beds that may be approved in excess of the bed need for each planning area identified in Appendix B is set forth in subsection (A).

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

(iii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements are met:

(A) The planning area in which the beds will be located shall have a population density of less than 28 individuals per square mile based on the 2000 U.S. Census figures as set forth in Appendix D.

(B) The applicant facility has experienced an average occupancy rate of 92% for the most recent 24 months based on the Department's "Staffing/Bed Utilization Ratios Report."

(2) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement

Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(B) electronic nurse call systems shall be required in all facilities;

(C) handrails shall be required on both sides of patient corridors; and

(D) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in Appendix B, unless the following is met:

(i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 7. Requirements for approval to relocate existing nursing home/HLTCU beds

Sec. 7. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:

(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.

(b) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds shall not require any ownership relationship.

(c) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located in the same planning area.

(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.

(e) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.

(f) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.

(2) An applicant proposing to add new nursing home/HLTCU beds, as the receiving existing nursing home/HLTCU under subsection (1), shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three

years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The approval of the proposed new nursing home/HLTCU beds shall not result in an increase in the number of nursing home beds in the planning area.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 8. Requirements for approval to replace beds

Sec. 8. An applicant proposing to replace beds must meet the following as applicable.

(1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUS and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all

licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The proposed project is either to replace the licensed nursing home/HLTCU to a new site or replace a portion of the licensed beds at the existing licensed site.

(c) The proposed site is within the replacement zone.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(2) An applicant proposing to replace a licensed nursing home/HLTCU outside the replacement zone shall demonstrate all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply set forth in Appendix B.

(c) The number of beds to be replaced is equal to or less than the number of currently licensed beds at the nursing home/HLTCU at which the beds proposed for replacement are currently located.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B if the applicant demonstrates all of the following:

(a) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(a) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(b) electronic nurse call systems shall be required in all facilities;

(c) handrails shall be required on both sides of patient corridors; and

(d) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.

(c) The proposed project shall be within the replacement zone unless the applicant demonstrates all of the following:

(i) The proposed site for the replacement beds is in the same planning area, and not within a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including approved projects) within five calendar years prior to the date of the application,

(ii) The applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and

(iii) The current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(d) An approved project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 9. Requirements for approval to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU

Sec. 9. An applicant proposing to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU must meet the following as applicable:

(1) An applicant proposing to acquire an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home or HLTCU is located if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the state of Michigan for quality assurance assessment program (QAAP) OR civil monetary penalties (CMP).

(b) The acquisition will not result in a change in bed capacity.

(c) The licensed site does not change as a result of the acquisition.

(d) The project is limited solely to the acquisition of a nursing home/HLTCU with a valid license.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department, and

(f) The applicant shall participate in a quality improvement program, such as My Innerview, Advancing Excellence, or another comparable program for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Systems, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(2) An applicant proposing to acquire an existing nursing home/HLTCU approved pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) An applicant will continue to operate the existing nursing home/HLTCU pursuant to the new design model requirements.

(c) The applicant shall participate in a quality improvement program, such as My Innerview, Advancing Excellence, or another comparable program for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Systems, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(d) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home/HLTCU is located, if the applicant demonstrates all of the following:

(a) The lease renewal will not result in a change in bed capacity.

(b) The licensed site does not change as a result of the lease renewal.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 10. Review standards for comparative review

Sec. 10. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a)~~,~~ and (b).

(a) A qualifying project will be awarded points~~, in accordance with the schedule set forth below~~AS FOLLOWS:

(i) For an existing nursing home/HLTCU, the current percentage of ~~the nursing home's/HLTCU's~~ patient days of care reimbursed by Medicaid for the most recent 12 months of operation.

(ii) For a new nursing home/HLTCU, the proposed percentage of ~~the nursing home/HLTCU's~~ patient days of care to be reimbursed by Medicaid in the second 12 months of operation following project completion~~, and annually, thereafter, for at least seven years~~.

Percentage of Medicaid Patient Days (calculated using total patient days for all existing and proposed beds at the facility)	Points Awarded	
	CURRENT	PROPOSED
~~0~~	~~0~~	
~~1 – 19~~	~~3~~	
20 – ~~39~~59%	6	3
~~40 – 59~~	~~9~~	
60 – 100	~~12~~10	5

(b) A qualifying project will be awarded points as follows:

(i) Nine (9) points if~~,~~ 100%, six (6) points if 75%, and ~~three~~ FOUR (~~3~~4) points if 50% of the licensed nursing home beds at the facility are Medicaid certified for the most recent 12 months for an existing nursing home/HLTCU.

(ii) ~~Nine~~ SEVEN (~~9~~7) points if 100%, ~~six~~ FOUR (4) points if 75%, and ~~three~~ TWO (~~3~~2) points if 50% of the proposed beds at the facility will be Medicaid certified for a new nursing home/HLTCU.

(3) A qualifying project will be awarded points~~, in accordance with the schedule set forth below,~~ based on the most recent 12 months of participation level in the Medicare program for an existing nursing home/HLTCU and the proposed participation level for a new nursing home/HLTCU.

Participation Level	Points Awarded
~~No Medicare certification of any physically conforming~~	~~0~~

~~existing and proposed beds.~~

Medicare certification of at least one (1) bed but less than 100% ~~of all physically conforming existing and proposed beds.~~ 1

Medicare certification of 100% of all ~~physically conforming~~ existing and proposed beds. ~~2~~3

(4) A qualifying project will ~~have~~ BE DEDUCTED 15 points ~~deducted based on~~IF the applicant~~'s record of compliance with applicable federal and state safety and operating standards for any nursing home/HLTCU owned and/or operated by the applicant in Michigan. Points shall be deducted in accord with the schedule set forth below if, after July 11, 1993, the records which are maintained by the Department document (a) any nonrenewal or revocation of license for cause and/or (b) nonrenewal or termination for cause of either Medicare or Medicaid certification of any Michigan nursing home/HLTCU owned and/or operated by the applicant.~~ AT THE TIME THE APPLICATION IS SUBMITTED:

~~Nursing Home/HLTCU Compliance Action~~	~~Points Deducted~~
~~Nonrenewal or revocation of license~~	~~4~~
~~Nonrenewal or termination of:~~	
~~Certification - Medicare~~	~~4~~
~~Certification - Medicaid~~	~~4~~

(A) IS CURRENTLY A SPECIAL FOCUS NURSING HOME/HLTCU AS IDENTIFIED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS);
(B) HAS BEEN A SPECIAL FOCUS NURSING HOME/HLTCU WITHIN THE LAST TWO YEARS.
(C) HAS HAD MORE THAN EIGHT (8) SUBSTANDARD QUALITY OF CARE CITATIONS; IMMEDIATE HARM CITATIONS, OR IMMEDIATE JEOPARDY CITATIONS IN THE THREE (3) MOST RECENT STANDARD SURVEY CYCLES (INCLUDES INTERVENING ABBREVIATED SURVEYS AND STANDARD SURVEYS);
(D) HAS HAD AN INVOLUNTARY TERMINATION OR VOLUNTARY TERMINATION AT THE THREAT OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT WITHIN THE LAST THREE (3) YEARS;
(E) HAS HAD A STATE ENFORCEMENT ACTION RESULTING IN A REDUCTION IN LICENSE CAPACITY OR A BAN ON ADMISSIONS WITHIN THE LAST THREE (3) YEARS; OR
(F) DOES HAVE ANY OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP), CIVIL MONETARY PENALTIES (CMP), MEDICAID LEVEL OF CARE DETERMINATION (LOCD), OR PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PSARR).

(5) A qualifying project will be awarded ~~nine (9)~~10 points if the applicant currently ~~provides~~ PARTICIPATES or ~~demonstrates that it will~~FIVE (5) POINTS IF IT PROPOSES TO participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. AN ADDITIONAL FIVE (5) POINTS WILL BE AWARDED IF THE CULTURE CHANGE MODEL, EITHER CURRENTLY USED OR PROPOSED, IS A MODEL IDENTIFIED BY THE DEPARTMENT.

(6) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the total proposed project cost ~~in accord with the schedule set forth below~~AS FOLLOWS:

Percentage "Applicant's Cash"	Points Awarded
Over 20~~ percent~~%	10
~~15.1 to 20 percent~~	~~8~~
10~~.1 to 15 percent~~ – 20%	6
5~~.1 to 10 percent~~ – 9%	4
~~1.1 to 5 percent~~	~~2~~
~~0 to 1 percent~~	~~0~~

(7) A qualifying project will be awarded six (6) points if the existing or proposed nursing home/HLTCU is fully equipped with sprinklers.

(8) A qualifying project will be awarded points based on the facility design of the existing or proposed nursing home:

Facility Design	Points Awarded
80% PRIVATE ROOMS WITH PRIVATE TOILET, SINK, AND SHOWER	10
80% private rooms with private toilet and sink, and central showers with adjacent private changing room for the resident to dress and undress in privacy	~~6~~5
~~80% private rooms with private toilet, sink, and shower~~	~~6~~
80% private rooms with private sink, shared toilet, and central showers with adjacent private changing room for the resident to dress and undress in privacy	3

(9) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE NURSING HOME/HLTCU OFFERS OR THREE (3) POINTS IF THE NURSING HOME/HLTCU PROPOSES AN ARRAY OF SERVICES THAT INCLUDES CHOICE IN LIVING ARRANGEMENTS (NURSING FACILITY, SUPPORTIVE LIVING ASSISTANCE, AND/OR INDEPENDENT HOUSING) AND PROMOTES AGING IN PLACE.

(10) A QUALIFYING PROJECT WILL BE AWARDED POINTS, FOR AN EXISTING OR PROPOSED NURSING HOME/HLTCU, AS FOLLOWS:

NUMBER OF BEDS	Points Awarded
100 BEDS OR LESS	10
101 – 150 BEDS	5
151 – 200 BEDS	3

(11) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF THE APPLICANT PROVIDES ITS AUDITED FINANCIAL STATEMENTS. AN ADDITIONAL FIVE (5) POINTS WILL BE AWARDED IF THE AUDITED FINANCIAL STATEMENTS SHOW A POSITIVE CASH FLOW BALANCE.

(12) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE PROPOSED BEDS WILL BE HOUSED IN NEW CONSTRUCTION.

(13) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU DOES NOT INCLUDE ANY 3- OR 4-BED WARDS.

(14) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS ON AN EXISTING PUBLIC TRANSPORTATION ROUTE AND FIVE (5) POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS NOT ON AN EXISTING ROUTE BUT SUPPLIES A LETTER OF SUPPORT FOR THE PROPOSED PROJECT FROM THE LOCAL PUBLIC TRANSPORTATION AUTHORITY.

(15) 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. ~~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.~~

(~~10~~16) 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, and which have the highest number of points when the results of subsections (2) through (~~9~~14) 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), in the order in which the applications were received by the Department, based on the date and time stamp on the application~~,~~ when the application is filed.

Section 11. Project delivery requirements -- terms of approval for all applicants

Sec. 11. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards, including the requirements of Section 10.

(b) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's

patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Community Health [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA provided to the Department by the Michigan Department of Community Health.

(c) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) for which the seller or other previous owner/lessee had been awarded points in a comparative review.

(d) Compliance with applicable operating standards.

(e) Compliance with the following quality assurance standards:

(i) For projects involving replacement of an existing nursing home/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(ii) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on an individual basis for each licensed site, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) The applicant shall provide the Department with a notice stating the date the beds are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.

(3) 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. Department inventory of beds

Sec. 12. The Department shall maintain a listing of the Department Inventory of Beds for each planning area.

Section 13. Wayne County planning areas

Sec. 13. (1) For purposes of these standards the cities and/or townships in Wayne County are assigned to the planning areas as follows:

<u>Planning Area 84/Northwest Wayne</u>

Canton Township, Dearborn, Dearborn Heights, Garden City, Inkster, Livonia, Northville (part), Northville Township, Plymouth, Plymouth Township, Redford Township, Wayne, Westland

Planning area 85/Southwest Wayne

Allen Park, Belleville, Brownstown Township, Ecorse, Flat Rock, Gibraltar, Grosse Ile Township, Huron Township, Lincoln Park, Melvindale, River Rouge, Riverview, Rockwood, Romulus, Southgate, Sumpter Township, Taylor, Trenton, Van Buren Township, Woodhaven, Wyandotte

Planning area 86/Detroit

Detroit, Grosse Pointe, Grosse Pointe Township, Grosse Pointe Farms, Grosse Pointe Park, Grosse Pointe Woods, Hamtramck, Harper Woods, Highland Park

Section 14. Health Service Areas

Sec. 14. Counties assigned to each of the HSAs are as follows:

HSA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	

7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 15. Effect on prior CON review standards, comparative reviews

Sec. 15. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on ~~March 11~~APRIL 30, 2008 and effective on June 20, 2008.

(2) Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows:

(a) replacement of an existing nursing home/HLTCU being replaced in a rural county;

(b) replacement of an existing nursing home/HLTCU in a micropolitan or metropolitan statistical area county that is within two miles of the existing nursing home/HLTCU;

(c) relocation of existing nursing home/HLTCU beds; or

(d) an increase in beds pursuant to Section 6(1)(d)(ii) or (iii).

(3) Projects reviewed under these standards that relate solely to the acquisition of an existing nursing home/HLTCU or the renewal of a lease shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The use rate per 1000 population for each age cohort, for purposes of these standards, until otherwise changed by the Commission, is as follows.

(i) age 0 - 64: 170 days of care

(ii) age 65 - 74: 3,126 days of care

(iii) age 75 - 84: 10,987 days of care

(iv) age 85 +: 37,368 days of care

APPENDIX B

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The bed need numbers, for purposes of these standards, until otherwise changed by the Commission, are as follows:

Planning Area	Bed Need	ADC Adjustment Factor
ALCONA	88	0.90
ALGER	68	0.90
ALLEGAN	426	0.95
ALPENA	173	0.95
ANTRIM	142	0.95
ARENAC	112	0.95
BARAGA	50	0.90
BARRY	252	0.95
BAY	552	0.95
BENZIE	118	0.95
BERRIEN	790	0.95
BRANCH	222	0.95
CALHOUN	651	0.95
CASS	234	0.95
CHARLEVOIX	152	0.95
CHEBOYGAN	181	0.95
CHIPPEWA	189	0.95
CLARE	163	0.95
CLINTON	268	0.95
CRAWFORD	104	0.95
DELTA	234	0.95
DICKINSON	174	0.95
EATON	472	0.95
EMMET	172	0.95
GENESEE	1,938	0.95
GLADWIN	170	0.95
GOGEBIC	114	0.95
GD. TRAVERSE	410	0.95
GRATIOT	255	0.95
HILLSDALE	218	0.95
HOUGHTON/KEWEENAW	168	0.95
HURON	226	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
INGHAM	1,161	0.95
IONIA	258	0.95
IOSCO	207	0.95
IRON	101	0.95
ISABELLA	244	0.95
JACKSON	794	0.95
KALAMAZOO	1,069	0.95
KALKASKA	81	0.90
KENT	2,388	0.95
LAKE	83	0.90
LAPEER	352	0.95
LEELANAU	136	0.95
LENAWEE	487	0.95
LIVINGSTON	592	0.95
LUCE	46	0.90
MACKINAC	79	0.90
MACOMB	4,305	0.95
MANISTEE	154	0.95
MARQUETTE	282	0.95
MASON	166	0.95
MECOSTA	212	0.95
MENOMINEE	140	0.95
MIDLAND	395	0.95
MISSAUKEE	91	0.90
MONROE	645	0.95
MONTCALM	253	0.95
MONTMORENCY	99	0.90
MUSKEGON	779	0.95
NEWAYGO	219	0.95
OAKLAND	5,326	0.95
OCEANA	124	0.95
OGEMAW	144	0.95
ONTONAGON	48	0.90
OSCEOLA	106	0.95
OSCODA	85	0.90
OTSEGO	139	0.95
OTTAWA	1,060	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
PRESQUE ISLE	115	0.95
ROSCOMMON	186	0.95
SAGINAW	1,039	0.95
ST. CLAIR	754	0.95
ST. JOSEPH	289	0.95
SANILAC	231	0.95
SCHOOLCRAFT	58	0.90
SHIAWASSEE	350	0.95
TUSCOLA	270	0.95
VAN BUREN	325	0.95
WASHTENAW	1,146	0.95
WEXFORD	168	0.95
NW WAYNE	2,563	0.95
SW WAYNE	1,732	0.95
DETROIT	4,435	0.95

APPENDIX C

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

APPENDIX D

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS

Michigan nursing home planning areas with a population density of less than 28 individuals per square mile based on 2000 U.S. Census figures.

Planning Area	Population Density Per Square Mile
Ontonagon	6.0
Schoolcraft	7.6
Luce	7.8
Baraga	9.7
Alger	10.7
Iron	11.3
Mackinac	11.7
Oscoda	16.7
Alcona	17.4
Gogebic	15.8
Montmorency	18.8
Lake	20.0
Presque isle	21.8
Menominee	24.3
Chippewa	24.7
Houghton/Keweenaw	24.7
Missaukee	25.5
Crawford	25.6

Source: Michigan Department of Management and Budget and the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS

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

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7, and 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:

(a) "Behavioral patient" means an individual that exhibits a history of chronic behavior management problems such as aggressive behavior that puts self or others at risk for harm, or an altered state of consciousness, including paranoia , delusions, and acute confusion.

(b) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 et seq.

(c) "Infection control program," means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(d) "Licensed hospital" means either a hospital licensed under Part 215 of the Code; or a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(e) "Private residence", means a setting other than a licensed hospital; or a nursing home including a nursing home or part of a nursing home approved pursuant to Section 6.

(f) "Traumatic brain injury (TBI)/spinal cord injury (SCI) patient" means an individual with TBI or SCI that is acquired or due to a traumatic insult to the brain and its related parts that is not of a degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(g) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory assistance.

Section 2. Requirements for approval -- applicants proposing to increase nursing home beds -- special use exceptions

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to this addendum.

Section 3. Statewide pool for the needs of special population groups within the long-term care and nursing home populations

Sec. 3. (1) A statewide pool of additional nursing home beds of 1,958 beds needed in the state is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated as follows:

(a) These categories shall be allocated 1,109 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):

(i) TBI/SCI beds will be allocated 400 beds.

(ii) Behavioral beds will be allocated 400 beds.

(iii) Hospice beds will be allocated 130 beds.

(iv) Ventilator-dependent beds will be allocated 179 beds.

(b) The following historical categories have been allocated 849 beds. Additional beds shall not be allocated to these categories. If the beds within any of these categories are delicensed, the beds shall be eliminated and not be returned to the statewide pool for special population groups.

(i) Alzheimer's disease has 384 beds.

(ii) Health care needs for skilled nursing care has 173 beds.

(iii) Religious has 292 beds.

(c) The number of beds set aside from the total statewide pool established for categories in subsection (1)(a) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.

(i) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.

(ii) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established for categories in subsection (1)(a).

(iii) The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established for categories in subsection (1)(a).

(iv) For purposes of this subsection, "application period" means the period of time from one designated application date to the next subsequent designated application date.

(v) For purposes of this subsection, "CON activity" means one or more of the following:

(A) CON applications for beds for a special population group have been submitted to the Department for which either a proposed or final decision has not yet been issued by the Department.

(B) Administrative hearings or appeals to court of decisions issued on CON applications for beds for a special population group are pending resolution.

(C) An approved CON for beds for each special population group has expired for lack of appropriate action by an applicant to implement an approved CON.

(d) By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds pursuant to sections 4, 5, 6, and 7. It does not preclude the care of these patients in units of hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with applicable statutory or certification requirements.

(2) Increases in nursing home beds approved under this addendum for special population groups shall not cause planning areas currently showing an unmet bed need to have that need reduced or planning areas showing a current surplus of beds to have that surplus increased.

Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to TBI/SCI patients

Sec. 4. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of TBI/SCI patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) A continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) A transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(2) Beds approved under this subsection shall not be converted to general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards for nursing home and hospital long-term care unit beds and shall not be offered to individuals other than TBI/SCI patients.

Section 5. Requirements for approval for beds from the statewide pool for special population groups allocated to behavioral patients

Sec. 5. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of behavioral patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) Individual units shall consist of 20 beds or less per unit.

(b) The facility shall not be awarded more than 40 beds.

(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.

(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.

(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(f) Staff will be specially trained in treatment of behavioral patients.

(2) Beds approved under this subsection shall not be converted to general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 6. Requirements for approval for beds from the statewide pool for special population groups allocated to hospice patients

Sec. 6. The CON Commission determines there is a need for beds for patients requiring both hospice and long-term nursing care services within the long-term care and nursing home populations.

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) An applicant shall be a hospice certified by Medicare pursuant to the Code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.

(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.

(c) An application shall propose 30 beds or less.

(d) An applicant for beds from the special statewide pool of beds shall not be approved if any application for beds in that same planning area has been approved from the special statewide pool of beds allocated for hospice.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 7. Requirements for approval for beds from the statewide pool for special population groups allocated to ventilator-dependent patients

Sec. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.

(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.

(c) The proposed unit will serve only ventilator-dependent patients.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 8. Acquisition of nursing home/HLTCU beds approved pursuant to this addendum

Sec. 8. (1) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to religious shall meet the following:

(a) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under section 501(c)(3) of the United States Internal Revenue Code.

(b) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.

(c) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.

(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(2) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to TBI/SCI shall meet the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) a continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) a transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(3) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall meet the following:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(g) Staff will be specially trained in Alzheimer's disease treatment.
(h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(4) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to behavioral patients shall meet the following:
(a) Individual units shall consist of 20 beds or less per unit.
(b) The facility shall not be awarded more than 40 beds.
(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.
(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.
(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
(f) Staff will be specially trained in treatment of behavioral patients.
(g) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(5) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to hospice shall meet the following:
(a) An applicant shall be a hospice certified by Medicare pursuant to the code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare Programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.
(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.
(c) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(6) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall meet the following:
(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.
(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.
(c) The proposed unit will serve only ventilator-dependent patients.
(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 9. Project delivery requirements -- terms of approval for all applicants seeking approval under Section 3(1) of this addendum

Sec. 9. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(2) An applicant for beds from the statewide pool for special population groups allocated to religious shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term of CON approval:
(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.

(3) An applicant for beds from the statewide pool for special population groups allocated to Alzheimer's disease shall agree that if approved:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(g) Staff will be specially trained in Alzheimer's disease treatment.

(4) An applicant for beds from the statewide pool for special population groups allocated to hospice shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.

(b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.

(c) An applicant shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.

(d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds.

(e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds.

(f) Nursing home beds shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

(g) An applicant shall agree that the nursing home beds shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.

(h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.

(i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.

(5) An applicant for beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.

(ii) A program director that is a registered nurse.

(b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:

(i) respiratory therapy.

(ii) occupational and physical therapy.
(iii) psychological services.
(iv) family and patient teaching activities.
(c) An applicant shall establish and maintain written policies and procedures for each of the following:
(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.
(ii) The transfer of patients requiring care at other health care facilities.
(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.
(iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.
(v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.
(d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:
(i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.
(ii) placement and care of urinary catheters.
(iii) care and use of thermometers.
(iv) care and use of tracheostomy devices.
(v) employee personal hygiene.
(vi) aseptic technique.
(vii) care and use of respiratory therapy and related equipment.
(viii) isolation techniques and procedures.
(e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the ventilator-dependent unit.
(f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.
(g) An applicant shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.
(h) An applicant shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.

(6) An applicant for beds from the statewide pool for special population groups allocated to TBI/SCI patients shall agree that if approved:
(a) An applicant shall staff the proposed unit for TBI/SCI patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:
(i) A medical director with specialized knowledge, training, and skills in the care of TBI/SCI patients.
(ii) A program director that is a registered nurse.
(iii) Other professional disciplines required for a multi-disciplinary team approach to care.
(b) An applicant shall establish and maintain written policies and procedures for each of the following:
(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for TBI/SCI patients. At a minimum, the criteria shall address the required medical stability and the need for ancillary services, including dialysis services.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge, including support services to be provided by transitional living programs or other outpatient programs or services offered as part of a continuum of care to TBI patients by the applicant.

(iv) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(v) Quality assurance and assessment program to assure that services furnished to TBI/SCI patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the TBI patient receiving such services.

(7) An applicant for beds from the statewide pool for special population groups allocated to behavioral patients shall agree that if approved:

(a) An applicant shall staff the proposed unit for behavioral patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of behavioral patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

(b) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for behavioral patients.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(iv) quality assurance and assessment program to assure that services furnished to behavioral patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the behavioral patient receiving such services.

(v) Orientation and annual education/competencies for all staff, which shall include care guidelines, specialized communication, and patient safety.

Section 10. Comparative reviews, effect on prior CON review standards

Sec. 10. (1) Projects proposed under Section 4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(2) Projects proposed under Section 5 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(3) Projects proposed under Section 6 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(4) Projects proposed under Section 7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on March 11, 2008 and effective on June 2, 2008.

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In 2005, I spoke before the Commission in support of Hillsdale Community Health Center's application for a fixed MRI. I remain grateful for the Commission's positive response to that request.

As the only hospital within Hillsdale County that provides continuous emergency care, the MRI unit has proven critically important, averaging nearly 5,000 tests annually. Area physicians and their patients clearly depend on this service.

Unfortunately, the .6 Tesla MRI approved by the Commission in 2005 is now out of date. The machine's advanced age requires weekly repairs, resulting in frequent cancelled appointments. The outdated technology no longer produces the test results many doctors require to make their diagnosis.

This combination of unreliable service and inadequate technology has resulted in

I respectfully request that the Commission clarify these apparently-conflicting rulings and apply the 2009 standard of 3,000 tests annually with 20,000 emergency room visits to all hospitals.

Should the Commission be unprepared to make such a rule change, I do request that the Hillsdale Community Health Center's previous exception for 4,000 tests per year be extended to the purchase of a new MRI that more suitably meets the needs of the people of Hillsdale County.

physicians increasingly referring patients to hospitals far removed from Hillsdale County.

Clearly, a more reliable and advanced machine is required for the Center to continue providing adequate care to the community.

The Center has identified the funding necessary to purchase a new fixed 1.5 Tesla MRI unit. Unfortunately, the path to Commission approval of such a purchase is unclear.

Previously, the Commission has indicated that facilities wishing to replace existing fixed units must have at least 6,000 uses per year. In 2009, however, the Commission ruled that *new* fixed MRIs must only perform 3,000 tests per year with 20,000 emergency room visits.

These rulings seem to have established a higher threshold for hospitals already operating a fixed MRI compared to those who are new to providing the service.

ForTec Companies
Forwarding Technology

June 7, 2010

Via E-mail (rogersbre@michigan.gov)

Michigan Certificate of Need Commission
Commissioner Ed Goldman
Attn: Brenda Rogers
Capitol View Building
201 Townsend
Lansing, MI 48913

Re: Deregulation of Lithotripsy

Ladies and Gentlemen:

Please find attached a Memorandum prepared by ForTec Companies in support of the repeal of Michigan's certificate of need review requirements for extracorporeal shockwave lithotripsy. A representative of ForTec plans to attend the June 10 Commission meeting, and would like to make a brief presentation at the meeting highlighting certain information in the attached Memorandum

Please contact me with any questions or comments you may have regarding the attached Memorandum.

Sincerely,

Drew C. Forhan
CEO

10125 Wellman Rd Streetsboro, OH 44241 p: 800.963.7101 f: 330.655.8894 w: forteccompanies.com

MEMORANDUM

To: Michigan Certificate of Need Commission; Commissioner Ed Goldman

From: ForTec Companies

Re: Repeal of Lithotripsy CON Review Requirements

This Memorandum supports the position of the Michigan Department of Community Health (MDCH) to repeal the Michigan Certificate of Need Requirements for urinary extracorporeal shockwave lithotripsy (UESWL). ForTec Companies is uniquely qualified to express its opinion on this subject as it presently operates 10 lithotripters in four states that perform over 4,000 lithotripsy procedures annually. ForTec utilizes only state of the art lithotripsy technology, and relies heavily on local physicians to identify the best technology to meet the needs of their patients. ForTec puts quality of patient care first. Its quality assurance program includes having a physician medical director review every lithotripsy procedure performed to (i) ensure proper equipment utilization, (ii) provide notification of physician result aberrations and suggest corrective action, (iii) provide published peer review literature to treating physicians to improve patient care, (iv) provide a review forum to address patient complications or aberrant results, and (v) create best practices for treating physicians.

The nine mobile lithotripters in Michigan average 1,100 treatments annually. Taking into account treatment times, travel between treatment sites, maintenance and scheduling irregularities, ForTec has found in its experience that to provide the best accessible patient care a lithotripter should provide between 500 to 700 treatments annually. Procedure volumes greater than that raise grave concerns regarding patient treatment delays, and their attendant risks of medical complications and pain for the patient. Repealing the lithotripsy CON will ensure more lithotripters providing services in Michigan, lower procedure volumes per machine, greater patient access and quicker patient treatment times. Often when patients have to wait for their lithotripsy procedure they have to be stented with anesthesia when they are diagnosed, and they run the risk of anesthesia again on a later date when they are treated with the lithotripter.

Removing the CON restrictions will certainly invite more competition into the Michigan market, and ForTec looks forward to the potential opportunity of serving patients in Michigan. Competition will mean greater access, lower competitive pricing of services and will bring market pressure to upgrade lithotripsy technology so that patients in Michigan receive the very best care.

In the April 28, 2010 MDCH Discussion Summary concerning the deregulation of lithotripsy, it was noted that New Jersey, West Virginia, New Hampshire, Illinois, Mississippi, Kentucky, Alabama and Georgia all recently deregulated lithotripsy from their CON programs. It should be noted that on June 10, 2010 the New York CON commission is also expected to remove lithotripsy from its CON review process as well.

Based on the information submitted above, we strongly encourage the Commission to repeal the CON for lithotripsy in Michigan, and we look forward to the potential opportunity of serving the citizens of Michigan.

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 is typically performed in an operating room and under the guidance of an anesthesiologist. It 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	Source:
17 States Total	Washington	American Health Planning Assoc.
*Coverage for mobile units only.	West Virginia	2009 National Directory
	Wisconsin	State Certificate of Need Programs
	20 States Total	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.

Lithotripsy CON Regulations by State Notes:

According to the information contained in the National Directory of Health Planning, Policy and Regulatory Agencies dating from 1995 to 2009 we found the following information:

- Alabama deregulated Lithotripsy from their CON regulations starting in 2004.
- Connecticut started regulating Lithotripsy under CON regulations in 1996 whereas in 1995 they were not regulated.
- Georgia has throughout the years has both regulated and not regulated Lithotripsy under their CON regulations. Most recently they are regulating it starting in 2006 after having not regulated it from 2003 through 2005.
- Illinois deregulated Lithotripsy from their CON regulations starting in 2000.
- Kentucky deregulated Lithotripsy from their CON regulations starting in 2005.
- Massachusetts started regulating Lithotripsy under CON regulations in 1996 whereas in 1995 they were not regulated.
- Mississippi deregulated Lithotripsy from their CON regulations starting in 2006.
- Nebraska regulated Lithotripsy in both 1996 & 1997 but not in 1995. They deregulated starting in 1998.
- New Hampshire deregulated Lithotripsy from their CON regulations starting in 2007.
- New Jersey deregulated Lithotripsy from their CON regulations starting in 2001.
- Oregon deregulated Lithotripsy from their CON regulations starting in 1996.
- Rhode Island deregulated Lithotripsy from their CON regulations starting in 1999.
- West Virginia was the state with the most recent deregulation of Lithotripsy taking place in 2009.

Lithotripsy CON Regulations by State

	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995
Alabama	**N**	**N**	**N**	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y	Y	Y	Y
Alaska	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Arizona															
Arkansas	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
California															
Colorado															
Connecticut	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	**N**
Delaware	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Dist. Of Columbia	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Florida	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Georgia	Y	Y	Y	Y	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y	Y	**N**
Hawaii	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
Idaho															
Illinois	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y
Indiana															
Iowa	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Kansas															
Kentucky	**N***	**N***	**N***	**N***	**N**	Y	Y	Y	Y	**N**	**N**	Y	Y	Y	Y
Louisiana	N	N	N	N	N	N	N	N	N	N	N	N/A	N	N	N
Maine	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Maryland	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Massachusetts	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	**N**
Michigan	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Minnesota															
Mississippi	**N**	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Missouri	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Montana	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Nebraska	N	N	N	N	N	N	N	N	N	N	N	N	**Y**	**Y**	N
Nevada	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
New Hampshire	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
New Jersey	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	Y	Y	Y	Y	Y	Y
New Mexico															
New York	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
North Carolina	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
North Dakota															

Lithotripsy CON Regulations by State

	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995
Ohio	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
Oklahoma	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Oregon	N	N	N	N	N	N	N	N	N	N	N	N	N	N	**Y**
Pennsylvania															
Rhode Island	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	Y	Y	Y	Y
South Carolina	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
South Dakota															
Tennessee	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Texas															
Utah															
Vermont	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Virginia	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Washington	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
West Virginia	**N**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Wisconsin	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
Wyoming															

* Lithotripsy is covered for mobile units.

1997 information was pulled from the seventh edition of the National Directory dated February 22, 1996.

Presented at the Certificate of Need (CON) Commission Meeting
June 10, 2010

CON Review Standards for Heart/Lung and Liver (HLL) Transplantation Services

At the request of the Commission, the Department again reviewed the definition of "initiate" or "implement." This review was done as a result of a request at the March 25, 2010, Commission meeting to modify the standards to permit a greater period of time for a HLL program to perform its first transplant procedure. The Department fails to see the need to propose language modifying the standards and, therefore, does not offer such.

The HLL standards already increases the typically allowed implementation requirements from a period of 12 months to 18 months for the first transplant. Furthermore, pursuant to administrative rule 325.9403, the applicant also has the ability to request an additional 6 month extension for a possible total of 24 months.

Two additional points that weighed into the Department's recommendation that no language be proposed at this time are that: 1) the HLL standards were recently modified with the new version effective on May 28, 2010, and 2) there is no opportunity for new HLL programs as the cap has been met. Modifying the standards would have no impact on the 3 existing HLL programs as they are already subject to the current standards and definitions.

Section 2. Definitions

Sec.2. (1) (g) "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.

Administrative Rules

R 325.9403 Term of certificate.

R403. (1) Unless otherwise specified in a certificate of need review standard, a certificate of need shall expire 1 year from its effective date, unless the project is implemented as defined in R 325.9103(b).

(2) The department, upon written request of the applicant, shall have 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 6 months if all of the following provisions are satisfied:
(a) The terms of the certificate are not changed.
(b) Substantial progress has been made.
(c) If applicable, an obligation for capital expenditure or establishment of a force account is likely to occur within the extended time period….

CARDIAC CATHETERIZATION SERVICES

CONSIDERATIONS FOR STANDARD ADVISORY COMMITTEE (SAC) DRAFT CHARGE

For Consideration by the CON Commission on June 10, 2010

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Whether or not cardiac catheterization services should continue to be regulated. If regulation of this service should be maintained, make recommendations, if necessary, regarding any modifications to the requirements. Further, if regulation is to be maintained, should the focus be on the types of service, i.e., diagnostic and therapeutic instead of equipment, i.e., the number of labs?

2. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services. If it is recommended that these services should be allowed, provide specific criteria for determining need for this service.

3. Review and recommend requirements for acquisition of services.

4. Review and update, if necessary, the methodology for determining procedure equivalents.

5. Review existing methodologies for determining need and update as appropriate.

6. Clarify what procedures shall count toward meeting volume requirements, including minimum volume requirements, specifically for diagnostic cardiac catheterization, therapeutic cardiac catheterization, and total laboratory volume requirements.

7. Review existing criteria, volume requirements, and procedure equivalents to determine necessary modifications, if any, related to new technology, evolving medical techniques, e.g., percutaneous insertion of cardiac valves, as well as changes in health care delivery.

8. Any technical or other changes from the Department, e.g., updates consistent with other CON review standards and the Public Health Code, separation of replace/upgrade.

CERTIFICATE OF NEED LEGAL ACTION

(6/10/10)

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).	Since no applicant appealed the Department's 2/10/10 final decision this matter will be closed and will not appear on future reports.

CERTIFICATE OF NEED LEGAL ACTION

(6/10/10)

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 dismiss their appeals. On May 24, 2010, the ALJ entered an order dismissing the appeals, with prejudice. We are currently awaiting a final decision from the Director.

CERTIFICATE OF NEED LEGAL ACTION

(6/10/10)

Macomb County - Compare Group # 950185 INCLUDES: 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 April 7, 2010, the Director of the Department issued her Final Order determining that the ALJ's Proposal for Decision in Macomb Comparative Appeal was correct. On April 19, 2010, one of the applicants in the Macomb Comparative Review filed a request for rehearing. This request was denied on April 30, 2010. The four unsuccessful applicants have filed separate administrative appeals in the Circuit Court. Three appeals have been filed in Macomb County Circuit Court and one has been filed in Ingham County Circuit Court.
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

(6/10/10)

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 May 18, 2010, the Director of the Department issued her Final Order determining that the ALJ's Proposal for Decision in Oakland Comparative Appeal was correct. The unsuccessful applicants have until 6/17/10 to file an appeal with the Circuit Court.
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.
Oakland County – Compare Group #950197 Includes: Medilodge of Novi CON App No: 09-0135 Heartland-West Bloomfield CON App No: 09-0140	04/07/10	Oakland County Comparative Review of nursing home beds – Administrative Appeal.	The parties agreed to stay this matter unlil resolution of Compare Group 95-0177.

CERTIFICATE OF NEED LEGAL ACTION

(6/10/10)

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. Awaiting scheduling of oral argument in consolidated case.

CON Leg Action; report 6/10/10

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 L

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	•	•	•	•	• F						
Bone Marrow Transplantation (BMT) Services	• R	•	• R	•	•	▮	▮	▮	▮	▮	▮	• —	•	P •	• ▲ F			• —	•	P •	• ▲ F			
Cardiac Catheterization Services															•	•	•	•	•	•	•	PH ▮	▮	▮
Computed Tomography (CT) Scanner Services										PH •	•	•	• R	•	•	•			▮	▮	▮	▮	▮	▮
Hospital Beds and Addendum for HIV Infected Individuals																						PH		
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	•	•	•	•	• R —	•	P •	• ▲ F			
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	•	•	• R						
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																					D			
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

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 June 10, 2010

Updated June 2, 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	May 28, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	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.