

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

Wednesday, June 21, 2006

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

APPROVED MINUTES

I. Call To Order.

Chairperson Hagenow called the meeting to order at 9:12 a.m.

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO (left at 3:49 p.m.)
Roger G. Andrzejewski
Bradley N. Cory (left at 2:01 p.m.)
Dorothy E. Deremo (arrived at 10:05 a.m. and left at 3:52 p.m.)
Marc Keshishian, MD
Adam Miller (Teleconference from 9:00 a.m. to 10:19 a.m.)
Michael A. Sandler, MD (left at 3:52 p.m.)
Kathie VanderPloeg-Hoekstra
Michael W. Young, DO

B. Members Absent:

None.

C. Department of Attorney General Staff:

Marvin Bromley (arrived at 9:35 a.m. and left at 2:02 p.m.)

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Jan Christensen
Sally Flanders
Tom Freebury
William Hart
John Hubinger
Matt Jordan
Irma Lopez
Bruce Matkovich
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers
Matt Weaver

II. Introduction of new CON Commissioners, all Commissioners, and CON Policy Staff.

Chairperson Norma Hagenow started the introductions with the three new Commissioners:

Kathie VanderPloeg-Hoekstra, Ship-Pac Inc.
Marc Keshishian, MD, Blue Care Network
Adam Miller, UAW

Following the introductions of the new Commissioners, the rest of the Commissioners introduced themselves.

Brenda Rogers introduced the newest member of the CON Policy Department:

Taleitha Pytlowanyj, Word Processing Assistant/Receptionist

The rest of the CON Policy Staff introduced themselves.

III. Review of Agenda.

Motion by Commissioner Goldman, seconded by Commissioner Young, to accept the Agenda with the modification of moving LTACHs to be discussed first followed by CT Scanner Services-Dental Scanner, then MRI Services and then BMT Services. Motion Carried.

IV. Declaration of Conflicts of Interest.

No conflicts were noted. Potential issues were noted from Commissioner Sandler on BMT and Commissioner Goldman on Dental CT and BMT.

V. Review of Minutes of March 21, 2006.

Commissioner Sandler made a request for a correction in the previous Minutes for the March 21, 2006 Meeting with the Conflicts of Interest. Commissioner Sandler's potential issue was with BMT and Commissioner Goldman's potential issues were with BMT and Dental CT.

Motion by Commissioner Ajluni, seconded by Commissioner Young, to accept the Minutes of March 21, 2006, with the modifications to the Conflicts of Interest. Motion Carried.

VI. Hospital Beds – Long Term (Acute) Care Hospitals (LTACHs) – Update.

Commissioner Goldman gave an update of the Workgroup. The Workgroup will continue and will have a report to present to the Commission at the next meeting. He reported that no action needs to be taken by the Commission at this time. No discussion followed.

VII. Computed Tomography (CT) Scanner Services – Dental Scanners Report (Attachment A).

A. Discussion.

Ms. Rogers provided an overview of the Computed Tomography (CT) Scanner Services-Dental Scanners Workgroup.

Commissioner Sandler gave an oral report of the discussion from the Dental CT Workgroup held on Wednesday, May 31, 2006. The Workgroup could not come to an agreement on several issues. The main items for the Workgroup to discuss regarding the language are what is an appropriate number of scans (taking into account referrals), the use of orthodontics as an indication, try to get it into less populated counties, making

sure any comments about Medicaid make sense, to define the HIPPA Privacy Regulations, and to look at a research exemption. Discussion followed.

B. Public Comment.

Sharon Brooks, DDS, University of Michigan
Larry Horwitz, Economic Alliance of Michigan
Glenn Melenyk, Blue Cross Blue Shield of Michigan
Cynthia Rider, DMD, Self
Ed Marandola, Imaging Sciences
Pedja Sukovic, Xoran Technologies
Robert Schwartz, Butzel Long

C. Commission Action.

Motion by Commissioner Sandler, seconded by Commissioner Cory, to approve for purposes of Public Hearing, the CON Standards for CT Scanners Services as amended for Dental CT Scanners using the number 200 for scans, defining HIPPA, adding research exemption language based upon other CON Review Standards, interested in Public Hearing comments regarding a change in the number 200 to lower number's, especially with reference to areas outside southeast Michigan, and to send it forward to the Joint Legislative Committee (JLC) for review. Motion Carried.

VIII. Magnetic Resonance Imaging (MRI) Services Workgroup Report.

A. Discussion.

Ms. Rogers provided an overview of the MRI Workgroup.

Commissioner Sandler gave an oral report of what the Workgroup discussed. The Workgroup had met once on May 16th. Commissioner Sandler stated that the main issues the Workgroup needs to focus on are research/clinical combined units, the rural multiplier, and the number of MRI's per county stipulation for conversion from mobile to fixed. Discussion followed.

B. Public Comment.

Walter Wheeler, Bell Memorial Hospital (written and oral testimony, Attachment B)
Jerry Morasko, Bell Memorial Hospital
Terry Gerald, Detroit Medical Center
Wilbur Smith, Wayne State University

Chairperson Hagenow paused the discussion of MRI Services for a moment to switch to BMT Services to allow Public Comment from people that were going to have to leave.

IX. Bone Marrow Transplantation (BMT) Services Workgroup Report.

A. Public Comment.

Joseph Uberti, Karmanos Cancer Center
Usha Sree Chamarchy, Sparrow Regional Cancer Center
Kenneth J. Matzick, President/CEO, Beaumont Hospitals (written testimony, Attachment C)
Representative John Garfield, Self and Wife (written and oral testimony, Attachment D)

Lunch Break from 12:15 p.m. to 1:04 p.m.

X. Magnetic Resonance Imaging (MRI) Services Workgroup Report Continued.

B. Public Comment.

Robert Meeker, Spectrum Health
Larry Horwitz, Economic Alliance of Michigan
Dennis Boe, Marquette General Hospital

C. Commission Action.

No action taken by the Commission. Commissioner Sandler would like the Workgroup to meet again. He will have a report to present to the Commission at the next meeting on September 19, 2006.

XI. Nursing Home and Hospital Long-term Care Unit Beds – Update.

A. Discussion.

Mr. Jan Christensen provided an update. The Workgroup had met three times and the language (Attachment E) being presented today was a result of those meetings. He stated that the Commission may delay action until September given the late submission of the language to allow adequate time for everyone to look over the language before making a decision.

Commissioner Cory gave a brief report. He recommended that action be postponed until September.

B. Public Comment.

Sarah Slocum, State Long Term Care Ombudsman (written and oral testimony, Attachment F)
Andrew Farmer, AARP Michigan (written testimony, Attachment G)
David Herbel, MAHSA
Reginald Carter, Health Care Association of Michigan (written and oral testimony, Attachment H)
Alison Hirschel, Michigan Advocacy Projects and Michigan Campaign for Quality Care
(written testimony, Attachment I)

C. Commission Action.

No action taken.

XII. Bone Marrow Transplantation (BMT) Services Workgroup Continued.

A. Discussion.

Ms. Rogers gave an introduction and summary of the Workgroup.

Commissioner Young gave an update on the Workgroup's progress. He stated that the Workgroup plans to meet again on July 14, 2006. The biggest issue that the Workgroup faces is the restriction on the number of BMT Services. Discussion Followed.

B. Public Comment.

Robert Asmussen and Ayad Al-Katib, St. John Health (written and oral testimony, Attachment J)
Robert Meeker, Spectrum Health (written and oral testimony, Attachment K)
Liz Palazzolo, Henry Ford Health System
Patrick O'Donovan, Beaumont Hospitals

Barbara Jackson, Economic Alliance of Michigan
Lakshmi Amarnath, CON Policy (written testimony, Attachment L)
Samuel M. Silver, MD, PhD, University of Michigan (written testimony, Attachment M)

C. Commission Action.

No action taken. The Workgroup will continue its work and will present its report in September.

XIII. Psychiatric Beds and Services Workgroup – Update (Attachment N)

Commissioner Deremo gave an oral report of the Workgroup. She stated that the Workgroup has met two times. Some of the issues that they are reviewing are the possibility of using the HSA's to define the planning areas, relocation language, and applying real life situations against any draft language. The Workgroup would like to have more people from small or low occupancy facilities as well as non-provider organizations represented at the meetings. Discussion followed.

XIV. Review of Charge for Cardiac Catheterization Services (Attachment O).

A. Discussion.

Ms. Rogers gave an overview of the Charge. Discussion followed.

B. Public Comment.

Cheryl Miller, Trinity Health (written and oral testimony, Attachment P)
Larry Horwitz, Economic Alliance of Michigan

C. Commission Action.

Motion by Commissioner Goldman, seconded by Commissioner Deremo, to accept the Cardiac Catheterization Services Charge with the modification of adding items 3, 4 and 5 as follows:

3. Consider new and emerging technology.
4. How to demonstrate need and compliance looking at geographic locations, volume, and types of procedures.
5. Report to the Commission at the December 12, 2006 meeting about any additional priority issues not in the Charge.

Motion Carried.

XV. Review of Charge for Open Heart Surgery Services (Attachment Q).

A. Discussion.

B. Public Comment.

Cheryl Miller, Trinity Health (written and oral testimony, Attachment R)
Robert MacKenzie, St. Mary's of Michigan
Larry Horwitz, Economic Alliance of Michigan

C. Commission Action.

Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the Open Heart Services Charge with the modification of adding items 3, 4 and 5 as follows:

3. Review and consider mandating the participation in a quality/risk adjusted outcome/database.
4. Report to the Commission at the December 12, 2006 meeting about any additional priority issues not in the Charge.
5. How to demonstrate need and compliance looking at geographic locations, volume, length of commitment, and types of procedures.

Motion Carried.

XVI. New Medical Technology Report.

Ms. Rogers reported no new medical technology.

XVII. Legislative Report.

Mr. Christensen reported no current legislative activity.

XVIII. Compliance Report.

Mr. Christensen reported that there are two Open Heart Surgery Centers that are currently out of compliance. One of the centers will be in compliance though, in about one or two months. The other one continuously is out of compliance. They are working with the facility to try to fix the problem. They are hoping to find a solution soon.

XIX. CON Program Update.

A. Online Application System.

Mr. Horvath provided an update on the CON Program's online application system. He gave a demonstration showing where and how to access the Letter of Intent on their website. The Department is working on trying to reduce the amount of paperwork for everyone. You can now go to their website, www.michigan.gov/con, and check on the status of an application by clicking on Online LOI Access/Registration.

B. Quarterly Performance Measures (Attachment S).

Mr. Horvath stated that the CON Program Section will report on their performance on a quarterly basis.

XX. Administrative Update.

Mr. Hart gave an update on the Workgroup process.

XXI. Future Meeting Dates.

September 19, 2006
December 12, 2006

XXII. Public Comment.

Mark Hutchinson, St. Mary's Health Care
Larry Horwitz, Economic Alliance of Michigan

XXIII. Review of Commission Work Plan (Attachment T).

Ms. Rogers provided a brief overview based on the draft provided and today's meeting discussions/actions.

Motion by Commissioner Goldman, seconded by Commissioner Keshishian, to accept the Work Plan as proposed. Motion Carried.

XXIV. Adjournment.

Motion by Commissioner Hagenow, seconded by Commissioner Goldman, to adjourn the meeting at 4:10 p.m. Motion Carried.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

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

(3) The department shall use sections 3, 4, 5, 6, 13, and 14, 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 sections 11 and 12, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit.

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

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

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

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

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

(h) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 9.

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

(j) "CT scanner equipment," for purposes of sections 3 and 5 of these standards, means the equipment necessary to perform CT scans. It does not include any construction or renovations activities associated with the installation of the CT scanner, or service or maintenance contracts which under generally accepted accounting principles are properly chargeable as an expense of operation.

(K) "DENTAL CT IMAGES", FOR THE PURPOSE OF SECTIONS 3 AND 11 OF THESE STANDARDS, MEANS USE OF A CT UNIT SPECIALLY DESIGNED TO GENERATE CT IMAGES TO FACILITATE DENTAL PROCEDURES.

55 (L) "DENTAL PROCEDURES", FOR THE PURPOSE OF SECTIONS 3 AND 11 OF THESE
 56 STANDARDS, MEANS DENTAL IMPLANTS, WISDOM TEETH SURGICAL
 57 PROCEDURES, MANDIBULAR OR MAXILLARY SURGICAL PROCEDURES, OR
 58 TEMPORAL MANDIBULAR JOINT EVALUATIONS.

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

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

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

65 (~~p~~P) "Expand a CT scanner service" means the addition of one or more CT scanners at an existing CT
 66 scanner service.

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

69 (R) "HIPAA" MEANS (TO BE DEFINED BY DEPARTMENT AT LATER DATE).

70 (~~p~~S) "Host facility" means the site at which a mobile CT scanner is located in order to provide CT
 71 scanner services.

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

76 (~~f~~U) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
 77 and 1396r-8 to 1396v.

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

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

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

88 (~~v~~Y) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is
 89 authorized to serve.

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

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

96 (~~y~~BB) "Replace/upgrade a CT scanner" means an equipment change proposed by an applicant which
 97 results in that applicant operating the same number of CT scanners before and after project completion.

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

103
 104 (2) The definitions in Part 222 shall apply to these standards.
 105
 106
 107
 108

109 **Section 3A. Requirements for approval for applicants proposing to initiate a CT scanner service**
 110 OTHER THAN A DENTAL CT

111
 112 Sec. 3. In order to be approved, an applicant proposing to initiate a CT scanner service shall
 113 demonstrate each of the following, as applicable:

114
 115 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the
 116 following:

- 117 (a) The proposed site is a hospital licensed under Part 215 of the Code.
 118 (b) The hospital operates an emergency room that provides 24-hour emergency care services as
 119 authorized by the local medical control authority to receive ambulance runs.

120
 121 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
 122 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT
 123 equivalents per year for the second 12 month period after beginning operation of the CT scanner.

124
 125 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of
 126 at least 3,500 CT equivalents per year for the second 12 month period after beginning operation of the CT
 127 scanner.

128
 129 SECTION 3B. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO INITIATE A
 130 DENTAL CT SCANNER SERVICE

131
 132 SEC. 3B. IN ORDER TO BE APPROVED, AN APPLICANT PROPOSING TO INITIATE A DENTAL CT
 133 SCANNER SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE:

134
 135 (1) THE APPLICANT IS PROPOSING A FIXED CT SCANNER SERVICE FOR THE SOLE
 136 PURPOSE OF GENERATING DENTAL CT IMAGES.

137 (2) THE CT SCANNER GENERATES A PEAK POWER OF 5 KILOWATTS OR LESS AS
 138 CERTIFIED BY THE MANUFACTURER.

139 (3) THE APPLICANT HAS DEMONSTRATED THAT THEY WILL PERFORM 200 DENTAL CT
 140 IMAGES FOR FACILITATING DENTAL PROCEDURES BY A COMBINATION OF THE FOLLOWING
 141 FOR THE MOST RECENT 12 MONTH PERIOD IMMEDIATELY PROCEEDING THE DATE OF THE
 142 APPLICATION:

143 (A) THE NUMBER OF DENTAL PROCEDURES PERFORMED BY THE APPLICANT, AND

144 (B) THE NUMBER OF DENTAL PROCEDURES PERFORMED BY REFERRING LICENSED
 145 DENTISTS WHO COMMIT TO REFER THAT NUMBER OF CASES TO THE APPLICANT FOR A
 146 DENTAL CT SCAN.

147 (C) THE APPLICANT AND THE REFERRING DENTISTS SHALL SUBSTANTIATE THE NUMBERS
 148 IN SUBDIVISIONS (A) OR (B) ABOVE, THROUGH SUBMISSION OF HIPAA COMPLIANT BILLING
 149 RECORDS.

150 (D) THE APPLICANT AND REFERRING DENTISTS, FOR THE PURPOSES OF SUBDIVISIONS (A)
 151 OR (B) ABOVE, HAS DEMONSTRATED TO THE SATISFACTION OF THE DEPARTMENT THAT THE
 152 PERSONS (E.G. TECHNICIAN AND/OR DENTIST) OPERATING THE CT SCANNER HAS BEEN
 153 APPROPRIATELY TRAINED AND/OR CERTIFIED BY ONE OF THE FOLLOWING GROUPS, AS
 154 RECOGNIZED BY THE DEPARTMENT: A DENTAL RADIOLOGY PROGRAM IN A CERTIFIED
 155 DENTAL SCHOOL, AN APPROPRIATE PROFESSIONAL SOCIETY, OR A DENTAL CONTINUING
 156 EDUCATION PROGRAM ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION.

157 (E) THE APPLICANT HAS DEMONSTRATED TO THE SATISFACTION OF THE DEPARTMENT
 158 THAT THE SCANS GENERATED BY THE PROPOSED CT SCANNER WILL BE INTERPRETED BY A
 159 PRACTITIONER TRAINED AND/OR CERTIFIED BY ONE OF THE FOLLOWING GROUPS, AS
 160 RECOGNIZED BY THE DEPARTMENT: A DENTAL RADIOLOGY PROGRAM IN A CERTIFIED
 161 DENTAL SCHOOL, AN APPROPRIATE PROFESSIONAL SOCIETY, OR A DENTAL CONTINUING
 162 EDUCATION PROGRAM ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION.

163
164 **Section 4. Requirements to expand a CT scanner service - all applicants**
165

166 Sec. 4. (1) If an applicant proposes to expand a fixed CT scanner service, the applicant shall
167 demonstrate each of the following:

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

171 (b) All of the applicant's fixed CT scanners have performed an average of at least 10,000 CT
172 equivalents per fixed CT scanner for the most recent continuous 12-month period preceding the
173 applicant's request. In computing this average the department will divide the total number of CT
174 equivalents performed by the applicant's total number of fixed CT scanners, including both operational
175 and approved but not operational fixed CT scanners.

176
177 (2) If an applicant proposes to expand a mobile CT scanner service, the applicant shall demonstrate
178 each of the following:

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

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

187
188 **Section 5. Requirements for applications proposing to replace/upgrade a CT scanner**
189

190 Sec. 5. In order to be approved, an applicant proposing to replace/upgrade an existing CT scanner
191 shall demonstrate each of the following, as applicable:
192

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

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

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

198 (c) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.
199

200 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),
201 proposing to replace/upgrade an existing fixed CT scanner shall demonstrate that the volume of CT
202 equivalents, during the 12-month period immediately preceding the date of the application, performed by
203 the CT scanner to be replaced/upgraded was at least 7,500 CT equivalents if the applicant operates only
204 one fixed CT scanner, or an average of 7,500 CT equivalents for each fixed CT scanner if the applicant
205 operates more than one fixed CT scanner at the same site.
206

207 (3) An applicant proposing to replace/upgrade an existing mobile CT scanner(s) shall demonstrate
208 that the volume of CT equivalents, during the 12-month period immediately preceding the date of the
209 application, performed by the CT scanner to be replaced/upgraded was at least 3,500 CT equivalents if
210 the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT
211 scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner
212 network.
213

214 (4) An applicant under this section shall demonstrate that the CT scanner(s) proposed to be
215 replaced/upgraded is fully depreciated according to generally accepted accounting principles, or, that the
216 existing equipment clearly poses a threat to the safety of the public, or, that the proposed

217 replacement/upgraded CT scanner offers technological improvements which enhance quality of care,
218 increase efficiency, and/or reduce operating costs and patient charges.
219

220 **Section 6. Requirements for approval for applicants proposing to relocate an existing CT scanner**
221 **service**

222 Sec. 6. An applicant proposing to relocate its existing CT scanner service and its unit(s) shall
223 demonstrate that the proposed project meets all of the following:
224

225 (1) The CT scanner service and its unit(s) to be relocated is a fixed CT scanner unit(s).
226

227 (2) The CT scanner service to be relocated has been in operation for at least 36 months as of the
228 date an application is submitted to the Department.
229

230 (3) The proposed project will not result in the replacement of the CT scanner unit(s) of the service to
231 be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, also
232 have been met.
233

234 (4) The proposed project will not result in an increase in the number of fixed unit(s) being operated
235 by the CT scanner service that is proposed to be relocated.
236

237 (5) The proposed site to which the CT scanner service is proposed to be relocated is in the relocation
238 zone.
239

240 (6) The CT scanner service and its unit(s) to be relocated performed at least an average of 7,500 CT
241 equivalents per fixed unit in the most recent 12-month period, or most recent annualized 6-month period,
242 for which the Department has verifiable data.
243

244 (7) The applicant agrees to operate the CT scanner service and its unit(s) in accordance with all
245 applicable project delivery requirements set forth in Section 11 of these standards.
246

247 **Section 7. Requirements for approval for applicants proposing to acquire an existing CT scanner**
248 **service and its unit(s)**

249 Sec. 7. An applicant proposing to acquire an existing fixed or mobile CT scanner service and its unit(s)
250 shall demonstrate that a proposed project meets all of the following:
251

252 (1) The project will not result in the replacement of the CT scanner unit at the CT scanner service to
253 be acquired unless the applicant demonstrates that the requirements of Section 5, as applicable, also
254 have been met.
255

256 (2) The project will not result in a change in the site at which the existing CT scanner service and its
257 unit(s) is operated unless the proposed project meets the requirements of Section 6.
258

259 (3) The project will not change the number of CT scanner unit(s) at the site of the CT scanner service
260 being acquired unless the applicant demonstrates that project is in compliance with the requirements of
261 Section 4 as applicable.
262

263 (4) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner
264 service, for which a final decision has not been issued after the effective date of these standards, an
265 existing CT scanner service to be acquired shall not be required to be in compliance with the volume
266 requirement applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service
267 and its unit(s) shall be operating at the applicable volume requirements set forth in Section 11 of these
268 standards in the second 12 months after the date the service and its unit(s) is acquired, and annually
269 thereafter.
270
271
272

273 (5) For any application for proposed acquisition of an existing fixed or mobile CT scanner service,
 274 except the first application approved pursuant to subsection (4), for which a final decision has not been
 275 issued after the effective date of these standards, an applicant shall be required to demonstrate that the
 276 CT scanner service and its unit(s) to be acquired performed at least 7,500 CT equivalents in the most
 277 recent 12-month period, or most recent annualized 6-month period, for which the Department has
 278 verifiable data.

279
 280 **Section 8. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,**
 281 **and acquisition**

282
 283 Sec. 8. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall
 284 demonstrate that it meets all of the following:

285
 286 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance
 287 with all applicable project delivery requirements as set forth in the CON review standards for PET.

288
 289 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project
 290 delivery requirements set forth in Section 11 of these standards.

291
 292 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.

293
 294 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services
 295 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid
 296 unit to demonstrate need or to satisfy CT CON review standards requirements.

297
 298 **Section 9. Additional requirements for approval of a mobile CT scanner service**

299
 300 Sec. 9. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall
 301 demonstrate that it meets all of the following:

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

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

307 (c) The requirements of sections 3, 4, or 5, as applicable, have been met.

308
 309 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall
 310 demonstrate that it meets all of the following:

311 (a) Approval of the application will not result in an increase in the number of operating mobile CT
 312 scanners for the mobile CT scanner network unless the requirements of Section 4 have been met.

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

314
 315 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner
 316 network shall demonstrate that approval of the application will not replace the CT scanner and
 317 transporting equipment unless the applicable requirements of Section 5 have been met.

318
 319 **Section 10. Requirements for approval -- all applicants**

320
 321 Sec. 10. An applicant shall provide verification of Medicaid participation at the time the application is
 322 submitted to the Department. If the required documentation is not submitted with the application on the
 323 designated application date, the application will be deemed filed on the first applicable designated
 324 application date after all required documentation is received by the Department.

325
 326 **Section 11. Project delivery requirements--terms of approval for all applicants**

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Sec. 11. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards

(b) Compliance with applicable safety and operating standards

(c) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

(v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site or available through telecommunication capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A) within 24 hours.

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

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

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

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

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

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

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

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

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

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

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

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

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

398 (D) AN APPLICANT APPROVED UNDER SECTION 3B SHALL NOT BE REQUIRED TO BE IN
 399 COMPLIANCE WITH SUBSECTION (C) BUT SHALL BE IN COMPLIANCE WITH THE FOLLOWING
 400 QUALITY ASSURANCE STANDARDS:

401 (I) THE CT SCANNER SHALL BE OPERATING AT LEAST {WORKGROUP COMMITTEE FEELS
 402 NUMBER IS BETWEEN 100 AND 200} CT EQUIVALENTS PER YEAR FOR THE SECOND 12 MONTH
 403 PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER AND ANNUALLY THEREAFTER.

404 (II) THE CT SCANNER WILL BE USED FOR THE SOLE PURPOSE OF DENTAL CT IMAGES.

405 (III) THE APPLICANT SHALL DEMONSTRATE TO THE SATISFACTION OF THE DEPARTMENT
 406 THAT THE PERSONS (E.G. TECHNICIAN AND/OR DENTIST) OPERATING THE DENTAL CT
 407 SCANNER HAVE BEEN APPROPRIATELY TRAINED AND/OR CERTIFIED BY ONE OF THE
 408 FOLLOWING GROUPS, AS RECOGNIZED BY THE DEPARTMENT: A DENTAL RADIOLOGY
 409 PROGRAM IN A CERTIFIED DENTAL SCHOOL, AN APPROPRIATE PROFESSIONAL SOCIETY, OR A
 410 DENTAL CONTINUING EDUCATION PROGRAM ACCREDITED BY THE AMERICAN DENTAL
 411 ASSOCIATION.

412 (IV) THE APPLICANT SHALL DEMONSTRATE TO THE SATISFACTION OF THE DEPARTMENT
 413 THAT THE SCANS GENERATED BY THE CT SCANNER WILL BE INTERPRETED BY A LICENSED
 414 DENTIST TRAINED AND/OR CERTIFIED BY ONE OF THE FOLLOWING GROUPS, AS RECOGNIZED
 415 BY THE DEPARTMENT: A DENTAL RADIOLOGY PROGRAM IN A CERTIFIED DENTAL SCHOOL, AN
 416 APPROPRIATE PROFESSIONAL SOCIETY, OR A DENTAL CONTINUING EDUCATION PROGRAM
 417 ACCREDITED BY THE AMERICAN DENTAL ASSOCIATION.

418 (V) THE APPLICANT SHALL DEMONSTRATE TO THE SATISFACTION OF THE DEPARTMENT
 419 THAT THE DENTISTS USING THE DENTAL CT IMAGES FOR PERFORMING DENTAL
 420 PROCEDURES HAS HAD THE APPROPRIATE TRAINING AND/OR EXPERIENCE CERTIFIED BY
 421 ONE OF THE FOLLOWING GROUPS, AS RECOGNIZED BY THE DEPARTMENT: A DENTAL
 422 RADIOLOGY PROGRAM IN A CERTIFIED DENTAL SCHOOL, AN APPROPRIATE PROFESSIONAL
 423 SOCIETY, OR A DENTAL CONTINUING EDUCATION PROGRAM ACCREDITED BY THE AMERICAN
 424 DENTAL ASSOCIATION.

425 (VI) THE APPLICANT, TO ASSURE THAT THE CT SCANNER WILL BE UTILIZED BY ALL
 426 SEGMENTS OF THE MICHIGAN POPULATION, SHALL:

427 (A) NOT DENY CT SCANNER SERVICES TO ANY INDIVIDUAL BASED ON ABILITY TO PAY OR
 428 SOURCE OF PAYMENT;

429 (B) PROVIDE CT SCANNING SERVICES TO ANY INDIVIDUAL BASED ON THE CLINICAL
 430 INDICATIONS OF NEED FOR THE SERVICE; AND

431 (C) MAINTAIN INFORMATION BY PAYOR AND NON-PAYING SOURCES TO INDICATE THE
 432 VOLUME OF CARE FROM EACH SOURCE PROVIDED ANNUALLY.

433 COMPLIANCE WITH SELECTIVE CONTRACTING REQUIREMENTS SHALL NOT BE CONSTRUED
 434 AS A VIOLATION OF THIS TERM.

435 (VII) THE APPLICANT SHALL PARTICIPATE IN A DATA COLLECTION NETWORK ESTABLISHED
 436 AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY INCLUDE, BUT IS
 437 NOT LIMITED TO, ANNUAL BUDGET AND COST INFORMATION, OPERATING SCHEDULES,
 438 THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND DIAGNOSTIC INFORMATION, THE VOLUME OF
 439 CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES, AND OTHER DATA REQUESTED
 440 BY THE DEPARTMENT, AND APPROVED BY THE COMMISSION. THE APPLICANT SHALL
 441 PROVIDE THE REQUIRED DATA ON A SEPARATE BASIS FOR EACH SEPARATE AND DISTINCT
 442 SITE OR UNIT AS REQUIRED BY THE DEPARTMENT; IN A FORMAT ESTABLISHED BY THE
 443 DEPARTMENT; AND IN A MUTUALLY AGREED UPON MEDIA. THE DEPARTMENT MAY ELECT TO
 444 VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE RECORDS.

445 (VIII) EQUIPMENT TO BE REPLACED SHALL BE REMOVED FROM SERVICE.

446 (IX) THE APPLICANT SHALL PROVIDE THE DEPARTMENT WITH A NOTICE STATING THE DATE
 447 THE APPROVED CT SCANNER SERVICE AND ITS UNIT(S) IS PLACED IN OPERATION AND SUCH
 448 NOTICE SHALL BE SUBMITTED TO THE DEPARTMENT CONSISTENT WITH APPLICABLE STATUTE
 449 AND PROMULGATED RULES.

450 (X) AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS
 451 WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY
 452 THEREAFTER.

453
 454
 455 (2) The agreements and assurances required by this section shall be in the form of a certification
 456 authorized by the governing body of the applicant or its authorized agent.

457
 458 (3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA
 459 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

460
 461 **Section 12. Project delivery requirements - additional terms of approval for applicants involving**
 462 **mobile CT scanners**

463
 464 Sec. 12. (1) In addition to the provisions of Section 11, an applicant for a mobile CT scanner shall
 465 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the
 466 following terms of CON approval:

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

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

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

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

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

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

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

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

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

496 (j) The volume of utilization at each host facility shall be reported to the Department by the central
 497 service coordinator under the terms of Section 11(1)(c)(xi).
 498

499 (2) The agreements and assurances required by this section shall be in the form of a certification
 500 authorized by the owner or the governing body of the applicant or its authorized agent.
 501

502 Section 13. Determination of CT Equivalents

503
 504 Sec. 13. For purposes of these standards, CT equivalents shall be calculated as follows:

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

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

510 (c) The number of CT equivalents for each category shall be summed to determine the total CT
 511 equivalents for the time period specified in the applicable section(s) of these standards.
 512

514 Category	515 Number of Billable CT Procedures		516 Conversion Factor		517 CT Equivalents
517 Head Scans w/o Contrast	_____	X	1.00	=	_____
518 Head Scans with Contrast	_____	X	1.25	=	_____
519 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
520 Body Scans w/o Contrast	_____	X	1.50	=	_____
521 Body Scans with Contrast	_____	X	1.75	=	_____
522 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
523 TOTAL CT EQUIVALENTS					_____

525 Section 14. Documentation of projections

526
 527 Sec. 14. An applicant required to project volumes of service under sections 3 and 4 shall specify how
 528 the volume projections were developed. This specification of projections shall include a description of the
 529 data source(s) used, assessments of the accuracy of these data, and the statistical method used to make
 530 the projections. Based on this documentation the Department shall determine whether the projections
 531 are reasonable.
 532

533 **Section 15. Effect on prior CON review standards; comparative reviews**

534
535 Sec. 15. (1) These CON review standards supersede and replace the CON Review Standards for
536 Computed Tomography Scanners approved by the CON Commission on April 23, 1990 and effective
537 June 17, 1990.

538
539 (2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

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**CON REVIEW STANDARDS
FOR CT SCANNER SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

Certificate of Need Commission

Lansing, Michigan

June 21, 2006

Testimony on Need for Rural Amendment to MRI Standards

Good morning. My name is Walter Wheeler and I am here today on behalf of Bell Memorial Hospital to support a minor, yet nonetheless meaningful adjustment to the MRI Standards that the MRI Workgroup discussed at its meeting last month.

Bell Memorial Hospital – a 25 bed “Critical Access Hospital” located in Ishpeming is recognized by the state and federal government as a health services “safety net” to assure access to quality health care in its community. For Michigan to thrive, the promotion of accessible health care is critical for a number of reasons including:

- The state of a community’s health,
- The quality of life in all parts of Michigan; and
- Economic development in Michigan’s rural areas.

Among the spectrum of clinical services provided by the hospital, Bell Memorial provides orthopedic services – which is not necessarily when the patient needs an MRI – (especially in the case of emergencies). A continuously available fixed unit would allow Bell Memorial to provide MRI services more effectively and at less cost than mobile unit, available only a few days a month.

Under the current law, a mobile MRI unit is the only technology available because, as a rural hospital, Bell is unlikely to meet the 6,000 procedure threshold for conversion from a mobile unit to a fixed unit. When it comes to meeting the volume requirements for conversion from a mobile to a fixed MRI, rural hospitals are in a “catch-22” situation. It’s not uncommon for the cases requiring an MRI to be there, but if those cases do not coincide with a day that the mobile MRI unit is located at the hospital, the patient’s needs are not being served. A mobile unit, available only for a limited number of days in a month (and, as discussed below, cost prohibitive to have on a daily basis), is not at the hospital often enough to generate the volume needed to convert to a fixed unit.

A limited exception to address this problem was enacted in 2004 when the volume required to convert from a mobile to a fixed unit was reduced from 6,000 cases to 4,000 cases in limited situations. This exception, however, cannot be used if there is even ONE fixed anywhere in the entire county. In other words, if there is one fixed unit anywhere else in the county, there is no volume exception at all. The current language exclusively benefits only the first hospital in the county to file for fixed services, but excludes the second or third hospital in the rural county from this exception.

Like other persons appearing today, we strongly support a change to lower the conversion volume requirement to 4,000 for all hospitals located in rural or micropolitan counties – while maintaining the 15-mile radius to prevent the duplication of services in the same market. In our view, while retention of the 15-mile radius standard promotes a constructive disposition of healthcare resources, the county structure is arbitrary.

The reason the standards originally favored a mobile unit over fixed units was to contain MRI costs. This made sense when the cost of fixed unit was extremely high and the cost of shared mobile services was relatively low. But with today’s technology the cost of fixed MRI unit can actually be less than the cost of renting time on a mobile unit.

Attachment B

First, the cost of fixed units has gone way down. Second, mobile central service providers know that most host sites have no chance of converting to a fixed unit under the current standards and therefore have no competition and no incentive to reduce or contain costs. For example, Bell Memorial currently pays approximately \$4,000/day for the mobile unit and was advised that that rate can be expected to increase in the near term to over \$5,000.

The limitation on access to MRI has real impacts. In rural communities mobile MRI waiting lists can extend for appreciable periods of time. In many cases patients are required to travel to remote MRI units for service. It is particularly difficult for senior citizens to travel to distant cities for services in large, unfamiliar institutions.

The bottom line is that Michigan's rural and micropolitan communities can have greater access to quality MRI services at less cost if the standards are amended to remove the 1 per county limitation on conversion from mobile to fixed MRI units.

We ask you to amend the conversion volume requirement to 4,000 for all hospitals located in rural or micropolitan counties – while maintaining the 15-mile radius to prevent the duplication of services in the same market. This is common sense and totally consistent with the purposes of CON program to promote cost containment, quality improvement and access to needed services.

Thank you for your time

Beaumont Hospitals®

June 15, 2006

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, MI 48913

Re: Bone Marrow Transplantation Services (BMT)

Dear Certificate of Need Commissioners:

Beaumont has long been a strong supporter of certificate of need because we believe it is in the best interest of the citizens of the State in terms of helping to balance costs, quality and access to health care services. Michigan's C.O.N. program has a well-designed process for updating C.O.N. review standards, by virtue of PA 619's requirement that C.O.N. standards be reviewed by the Commission every three years. Since the June 2005 C.O.N. Commission meeting, Beaumont has been advocating that BMT standards be reviewed and updated to improve quality and access to BMT services at reasonable cost. Beaumont and others provided testimony at the January 31, 2006 public hearing on BMT services, and at the March 2006 C.O.N. Commission meeting the Commission established a Workgroup on BMT services. Commissioner Michael Young, D.O., has been appointed as the C.O.N. Commission Liaison for the BMT Workgroup, and the first workgroup meeting was held May 25, 2006. Commissioner Young will be providing a status report on this workgroup at the June 21 C.O.N. Commission meeting. As Dr. Young will likely report, the workgroup was divided along competitive lines regarding whether the BMT standards should be revised using a needs-based methodology.

The trend for many years in C.O.N. in Michigan has been to move away from identifying a fixed number of programs for C.O.N. covered services and toward an "institution specific" approach, whereby if an applicant can demonstrate need based on the patients it currently serves (or in combination with others), the applicant can qualify for the service. In fact, other than beds (hospital, NICU, nursing home, psychiatric), the ONLY C.O.N. standards besides BMT (out of 12) that identify a fixed number of programs is heart/lung/liver transplants. For example, pancreas transplantation services used to have a fixed limit of three programs for the State; 13 years ago in 1993, these standards were changed to an institution-specific, needs-based methodology based on the number of kidney transplants performed. **Accordingly, Beaumont**

Corporate Administration
3711 W. Thirteen Mile Rd.
Royal Oak, MI 48073-6769

Certificate of Need Commission
 c/o Brenda Rogers, Health Policy Section
 Re: Bone Marrow Transplantation Services (BMT)

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asks that the Commission endorse an approach to revising the BMT standards that is needs based, institution-specific and not subject to comparative review. In previous written communication to the Commission and the Department, Beaumont has suggested one such approach using tumor registry data. If such an endorsement is not provided, it is unlikely that the workgroup or even a SAC would adopt any methodology that would allow large programs like Beaumont (the largest cancer program in the State in terms of newly diagnosed patients) to qualify for BMT services.

Quite simply, the reason that the standards should be changed to allow Beaumont to offer BMT is to better serve the patients that already look to Beaumont for their care. Consider the following:

- In terms of volume, Beaumont diagnoses the most new cancer cases in the State. New cancer case data from tumor registries in Michigan are shown below for 2003 (most recent public data):

Tumor Registry	# New Cancer Cases
Beaumont	4,065
University of Michigan	3,927
Henry Ford	2,732
Spectrum	2,650
Harper/Karmanos	1,943
Oakwood	1,443
St. John	1,323

Source: American Cancer Society

- Oncologists at large cancer centers like Beaumont without a BMT program must refer patients to outside centers and outside physicians for this treatment. This interrupts their continuity of care and negatively impacts the strong doctor-patients relationships that are established. Even when a patient is referred to an outside BMT program, the patient sometimes does not go to the outside program because of the hardships involved or because he or she does not wish to leave the cancer program with which they are familiar and comfortable. And even when the patient does go to an outside center for BMT, patients can have severe negative experiences when needed BMT follow-up care is not readily available (see attached letter detailing the patient experience of Representative John Garfield). Note also that there are no BMT programs in the State to the north or east of Beaumont. Allowing Beaumont to offer BMT would allow us to better treat the patients who are already coming to us.

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Re: Bone Marrow Transplantation Services (BMT)

June 15, 2006
Page 3

- Based on our Tumor Registry figures, we estimate that Beaumont would perform 50-75 bone marrow transplants per year. Many of these patients are currently being referred to Karmanos and to a lesser extent U-M and out-of-state programs; however some of these patients are not currently accessing BMT services at all for the reasons discussed above. Regardless, the volume impact on existing programs in the State would be quite limited.
- According to the National Marrow Donor Program (NMDP), the number of bone marrow transplants performed in the U.S. is projected to grow. This growth will be fueled by the capability to now treat older patients, the use of a Donor Marrow Registry that increasingly allows non-sibling donor matches, and use of BMT for diseases that have not traditionally been treated with transplants (including lupis, rheumatoid arthritis, multiple sclerosis, renal cell carcinoma and other solid tumors, and sickle cell disease). BMT may also become a viable strategy for heart disease. Two physicians from existing BMT programs in the State have argued that BMT is not growing and may lose favor as a cancer treatment option and that the future for BMT volume is stable at best with potential for decline. In contrast, Beaumont transplant physicians believe this is an exciting time for transplant as a treatment option not only for an expanded number of cancer patients, but also for patients with other previously mentioned medical conditions.
- Studies on BMT outcomes have revealed that transplant success can be highly dependent on transplant timing. Establishing an initial treatment plan that includes a possible BMT reduces the chance that complications could prevent a patient from receiving a transplant when needed (Source: National Marrow Donor Program). Therefore, presence of a BMT program at large cancer centers will increase the likelihood that the most appropriate treatment planning will occur to include the potential for BMT. Proper treatment planning enables a patient to move quickly to transplant, if needed, before disease progresses or complications develop. The immediate availability of a complete range of oncology services, including BMT, ensures that a large number of patients will receive the right level of care at precisely the right time.
- The costs to develop and operate a new BMT program are dependent on the physical and programmatic resources that are already available at the institution. Beaumont already has in place most of the elements required for a successful BMT program, including two experienced bone marrow transplant physicians trained at Johns Hopkins. The two major capital investments required to initiate the program at Beaumont are a stem cell laboratory and HEPPA filters on an inpatient unit – at a total capital cost of less than \$2 million.

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
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- Some have argued that because existing programs are not at capacity, that no new programs should be added, especially in Southeast Michigan. As discussed above, this limitation causes significant hardships for patients and is not consistent with how other C.O.N. standards have been rewritten. For example, if an applicant can demonstrate need (using hospital discharge data), new lithotripsy services can be initiated, even if the existing lithotripsy services are not all operating at capacity. In addition, referrals to outside centers also require significant re-testing and re-staging. These tests add substantial costs to the health care system and impose unnecessary hardships for these patients.
- If the BMT standards are revised to include a needs-based, institution-specific methodology, there will not be a large proliferation of new BMT programs. In addition to the high “hurdle rate” that any such methodology would likely include, a major limiting factor is availability of transplant physicians. Also, a limited increase in BMT programs across the State would not have a significant impact on the quality of BMT services provided at existing centers, because the volumes at these centers will still far exceed the minimum volume levels specified in the existing BMT C.O.N. standards. In addition, in the unlikely event that Beaumont is unable to meet minimum volume requirements, we would not continue offering the service; note that when Beaumont’s heart-transplant program failed to meet minimum volumes, we voluntarily ended the program.

Note also that per the American Health Planning Association, only 17 states cover Bone Marrow Transplants under C.O.N. at all. And, there is no correlation between the number of BMT programs by state, and whether or not that state covers BMT under C.O.N. (Source: American Health Planning Association, NMDP Transplant Directory).

- A BMT program would also have a major positive impact on the academic/educational activities at the Hospital which are essential to the Hospital’s education and research mission. Beaumont-Royal Oak is the largest hospital in Michigan and is a tertiary academic medical center and research facility. Beaumont maintains an accredited Medical Oncology Fellowship Program. ACGME Oncology Fellowship requirements mandate training in bone marrow transplants. Currently, fellows must leave the institution to obtain this required training. A bone marrow transplant program would also offer new rotations for other Beaumont residents/fellows in the fields of internal medicine, family practice, infectious disease and radiation oncology – many of these physicians go on to practice medicine at Beaumont, with a service area of 2 million people.

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Re: Bone Marrow Transplantation Services (BMT)

June 15, 2006
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- Establishing a BMT program would have a major positive impact on medical research at Beaumont:
 - The National Cancer Institute has designated Beaumont as a Community Clinical Oncology Program (CCOP), and we currently have 245 open clinical trials in cancer research areas. Beaumont is an attractive research site because of the access we provide to a large number of patients.
 - Led by William O'Neill, M.D., Corporate Chief of Cardiology, Beaumont has an international reputation in the field of cardiology. Dr. O'Neill believes that stem cell transplantation is going to play a major role in the treatment of patients with coronary artery disease, and presence of a BMT program at Beaumont will help to advance the investigation of BMT as a treatment for heart disease. See attached letter of support from Dr. O'Neill. Without a BMT program, Beaumont would not have a stem cell lab, which would be needed to support stem cell research in the field of cardiology.
 - Beyond Beaumont, arbitrarily limiting the number of centers in Michigan which can perform transplants is a major hurdle in the research and development of potentially curable treatment options for otherwise disabling and life-threatening conditions.
- Finally, given the condition of Michigan's economy the State has embarked on a major initiative to diversify its economy and attract high paying jobs in growing knowledge-based fields such as biotechnology and medical devices and instrumentation. Beaumont is participating in these efforts (through partnerships with technology-based companies and participation in Automation Alley), and establishment of a BMT program will help to advance the State's capabilities in these emerging sectors.

In addition to Beaumont's above request for the Commission to endorse development of an institution-specific, needs-based methodology for BMT services, Beaumont also asks that the Commission immediately approve and move to public comment language that would allow for acquisition of an existing BMT program. While Beaumont still strongly supports moving forward with development of a needs-based methodology, acquisition would allow for redistribution of existing programs without increasing the number of C.O.N. approved programs- an option that is not currently permitted. Beaumont has provided language to the Department that would accommodate this.

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Re: Bone Marrow Transplantation Services (BMT)

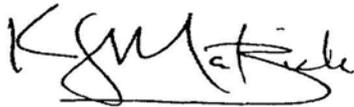
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In closing, Beaumont is seeking to serve its patients better and can do so with a capital investment of less than \$2 million. The cost impact to payors in the State will be minimal. Thank you for your consideration of this important patient care issue.

Sincerely,



Ronald B. Irwin, M.D.
Executive Vice President and Chief Medical Officer
(and practicing bone cancer surgeon)



Kenneth J. Matzick
President and Chief Executive Officer

lb
Attachments



45TH DISTRICT
P.O. BOX 30014
LANSING, MI 48909-7514
(517) 373-1773
1-877-JOHNG45
(564-6445)
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MICHIGAN HOUSE OF REPRESENTATIVES

JOHN GARFIELD
STATE REPRESENTATIVE

COMMITTEES:
VETERANS AFFAIRS AND
HOMELAND SECURITY – CHAIR
ENERGY AND TECHNOLOGY
TELECOMMUNICATIONS – CHAIR
CONSERVATION, FORESTRY, AND
OUTDOOR RECREATION
GOVERNMENT OPERATIONS

September 13, 2005

Certificate of Need Commission
Michigan Department of Community Health
320 South Walnut Street
Lewis Cass Building
Lansing, MI 48913

Dear Commissioners:

I am writing to support the request by Beaumont Hospitals that the Certificate of Need Commission establish a Standards Advisory Committee to review bone marrow and stem cell transplant services. I have a strong personal interest in seeing an increase in the availability of these programs in the state.

My wife was diagnosed with Amyloidosis, a rare blood disease, and received a stem cell transplant at Oakwood Hospital in 2004. There are no bone marrow or stem cell transplant programs in either Oakland or Macomb Counties, despite the fact that these procedures are now being used to treat more types of cancer than was the case when the current standards were adopted in 1997.

Last year, the day after my wife was discharged from Oakwood Hospital she went into metabolic shock entering a comatose like state. The nearest hospital to treat her condition, Oakwood, was 45 miles away from our home. Had either Oakland or Macomb Counties had the necessary treatment for my wife she would not have went into a comatose state, and nearly lost her life.

I recognize the importance of containing health care costs via the Certificate of Need program, but newer medical treatments must be accessible to our citizens. The lack of bone marrow and stem cell transplant programs limits treatment options for patients. As you can see from the signature below, there are legislators representing Oakland and Macomb Counties who would like to see an expanded bone marrow and stem cell transplant programs accessible not only in southeast Michigan, but across the entire state.

Thank you for your consideration.

Sincerely,

John Garfield
State Representative
45th District



MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS

FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

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

Section 1. Applicability

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

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

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

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

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

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

Section 2. Definitions

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

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

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

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

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

(e) "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.

(f) "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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

121 (z) "Nursing home" means a nursing care facility, including a county medical care facility, but
122 excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being
123 sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical
124 treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity

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

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

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

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

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

153 (ff) "Qualifying project" means each application in a comparative group which has been reviewed
154 individually and has been determined by the Department to have satisfied all of the requirements of Section
155 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable
156 requirements for approval in the Code and these standards.

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

160 (hh) "Replacement bed" means a nursing home bed with a valid license that meets all of the following
161 conditions: (i) an equal or greater number of nursing home beds are currently licensed to the applicant at
162 the licensed site at which the beds proposed for replacement are currently licensed, (ii) the nursing home
163 beds are proposed for replacement in new physical plant space being developed in new construction or in
164 newly acquired space (purchase, lease, donation, etc.), and (iii) the nursing home beds to be replaced will
165 be located in the replacement zone.

- 166 (ii) "Replacement zone" means a proposed licensed site that is,
 167 (i) for a rural or micropolitan statistical area county, within the same planning area as the existing
 168 licensed site.
 169 (ii) for a county that is not a rural or micropolitan statistical area county,
 170 (A) within the same planning area as the existing licensed site and
 171 (B) within a three-mile radius of the existing licensed site.
 172 (jj) "Room plan changes" means any construction activities in patient rooms, including bathroom
 173 areas, which involve moving walls. This does not include cosmetic renovations such as wallpaper,
 174 painting, carpeting, or other activities associated with normal wear and tear.
 175 (kk) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
 176 statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan
 177 statistical areas" by the statistical policy office of the office of information regulatory affairs of the United
 178 States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in
 179 Appendix C.
 180 (ll) "Staffing/Bed Utilization Ratios Report" means the report issued by the Department on a
 181 quarterly basis.
 182 (mm) "Total proposed project cost" means the total of all the items listed on the applicant's "Project
 183 Cost" form (form number T-150-G-11.02 or any subsequent replacement form) excluding the item "Pre-
 184 existing debt to be refinanced." For projects where existing beds/space are being converted to nursing
 185 home/HLTCU beds and the number of square feet of facility space to be allocated to the nursing
 186 home/HLTCU will increase, the imputed costs of the beds/space to be converted shall be determined
 187 based on a fair market value appraisal of the tangible assets to be converted. The imputed costs for the
 188 beds/space to be converted shall be entered on the "Project Cost" form on the line for "Construction Costs:
 189 Other."
 190 (nn) "Total proposed project cost per bed" is determined by dividing the applicant's "Total proposed
 191 project cost" by the applicant's proposed number of beds. The total proposed number of beds shall include
 192 new, replacement, and converted beds.
 193 (oo) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per
 194 1,000 population during a one-year period.
 195 (pp) "Vestibule" means a small entrance hall or passageway, between a common corridor and a
 196 patient room, of sufficient width and length to allow a corridor entrance door to swing in without obstruction.
 197 A vestibule also may provide an adequate area to permit an attached toilet room door sufficient clear swing
 198 space so as not to impact on minimum patient room net usable area requirements.
 199
 200 (2) The definitions in Part 222 of the Code shall apply to these standards.
 201

202 Section 3. Determination of needed nursing home bed supply

203
 204 Sec. 3 (1)(a) The age specific use rates for the planning year shall be the actual statewide age
 205 specific nursing home use rates using data from the base year.

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

208 (c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the
 209 use rates for the base year for each corresponding age cohort, established in accord with subsection (1)(b),
 210 are set forth in Appendix A.
 211

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

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

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

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

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

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

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

226 **Section 4. Bed need**

227
228
229 Sec. 4. (1) For purposes of these standards, until otherwise changed by the Commission, the bed
230 need numbers shown in Appendix B and incorporated as part of these standards shall apply to project
231 applications subject to review under these standards, except where a specific CON standard states
232 otherwise.

233
234 (2) The Commission may direct the Department to apply the bed need methodology in Section 3.

235
236 (3) The Commission shall designate the base year and the planning year that shall be utilized in
237 applying the methodology pursuant to subsection (2).

238
239 (4) When directed by the Commission to apply the methodology pursuant to subsection (2), the
240 effective date of the bed need numbers shall be established by the Commission.

241
242 (5) New bed need numbers established by subsections (2) and (3) shall supersede the bed need
243 numbers shown in Appendix B and shall be included as an amended appendix to these standards.

244
245 (6) Modifications made by the Commission pursuant to this section shall not require ad hoc advisory
246 committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in
247 order to become effective.

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

249
250
251 Sec. 5. (1) The Commission may modify the base year based on data obtained from the Michigan
252 Department of Community Health Annual Survey of Long-Term-Care Facilities or other comparable MDCH
253 survey instrument presented to the Commission by the Department. The Department shall calculate use
254 rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates
255 based on 1989 information, or the most recent base year information available biennially after 1989, to the
256 CON Commission.

257
258 (2) The Commission shall establish the effective date of the modifications made pursuant to
259 subsection (1).

260
261 (3) Modifications made by the Commission pursuant to subsection (1) shall not require ad hoc
262 advisory committee action, a public hearing, or submittal of the standard to the Legislature and the
263 Governor in order to become effective.

264 **Section 6. Requirements for approval - applicants proposing to increase beds in a planning area or 265 replace beds outside a replacement zone**

266
267
268 Sec. 6. (a) An applicant proposing to increase the number of nursing home beds in a planning area
269 must demonstrate that the proposed increase, if approved, will not result in the total number of existing
270 nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in
271 Appendix B. An applicant may request and be approved for up to a maximum of 20 beds if, when the total
272 number of "existing nursing home beds" is subtracted from the bed need for the planning area set forth in
273 Appendix B, the difference is equal to or more than 1 and equal to or less than 20.

274 This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

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

282 (c) An exception, NOT TO EXCEED 20 BEDS, to the number of beds that may be approved
 283 pursuant to subsection (a) or (b) shall be made if the requirements set forth in ~~both (i) and (ii) are~~ met.
 284 ~~The number of beds that may be approved in excess of the bed need for each planning area identified in~~
 285 ~~Appendix B is set forth in subsection (iii).~~

286 (i) The applicant requesting additional nursing home/HLTCU beds has experienced an AVERAGE
 287 occupancy rate, at the nursing home/HLTCU at which the additional beds are proposed, of at least 97.95%
 288 OF THE APPLICANT'S LICENSED BEDS for ~~each of the 1224 most recent~~ continuous quarters-MONTHS
 289 for which verifiable data are available to the Department on its "Staffing/Bed Utilization Ratios Report."

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

294 ~~— (iii) The number of beds that may be approved pursuant to this subsection shall be the number of~~
 295 ~~beds necessary to reduce the occupancy rate for the planning area in which the additional beds are~~
 296 ~~proposed to the ADC adjustment factor for that planning area as shown in Appendix B. The number of~~
 297 ~~beds shall be calculated by (1) dividing the actual number of patient days of care provided during the most~~
 298 ~~recent 12-month period for which verifiable data are available to the Department provided by all nursing~~
 299 ~~home (including HLTCU) beds in the planning area, including patient days of care provided in beds~~
 300 ~~approved from the statewide pool of beds and dividing that result by 365 (or 366 for leap years); (2) dividing~~
 301 ~~the result of step (1) by the ADC adjustment factor for the planning area in which the beds are proposed to~~
 302 ~~be added; (3) rounding the result of step (2) up to the next whole number; and (4) subtracting the total~~
 303 ~~number of beds in the planning area including beds approved from the statewide pool of beds from the~~
 304 ~~result of step (3). If the number of beds necessary to reduce the planning area occupancy rate to the ADC~~
 305 ~~adjustment factor for that planning area is equal to or more than 20, the number of beds that may be~~
 306 ~~approved pursuant to this subsection shall be up to that number of beds. If the number of beds necessary~~
 307 ~~to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is less than~~
 308 ~~20, the number of additional beds that may be approved shall be that number of beds or up to a maximum~~
 309 ~~of 20 beds.~~

310 (D) AN APPLICANT WHO HAS, AT THE TIME OF APPLICATION, ANY OF THE DEFICIENCY
 311 CONDITIONS LISTED BELOW FOR THE NURSING HOME IDENTIFIED IN THIS APPLICATION AND
 312 FOR ALL NURSING HOMES OWNED AND OPERATED BY THE APPLICANT AND THE APPLICANT'S
 313 OWNER, SHALL BE INELIGIBLE FOR A CON UNLESS 12 MONTHS HAS PASSED SINCE THE
 314 DEFICIENCY HAS BEEN REMEDIED AND SUCH REMEDY CONFIRMED IN WRITING BY THE
 315 DEPARTMENT:

316 (i) A STATE ENFORCEMENT ACTION INVOLVING LICENSE REVOCATION, A LIMITED OR
 317 TOTAL BAN ON ADMISSIONS, REDUCED LICENSE CAPACITY, SELECTIVE TRANSFER OF
 318 RESIDENTS, TEMPORARY MANAGER OR RECEIVERSHIP.

319 (ii) A CITATION FOR "IMMEDIATE JEOPARDY" UNDER THE FEDERAL REGULATORY
 320 REQUIREMENTS FOR NURSING HOMES.

321 (iii) TWO (2) OR MORE CITATIONS WITH THE SAME FEDERAL REGULATORY GROUPING AT
 322 HARM LEVELS SCOPE AND SEVERITY RATINGS G, H, I ISSUED WITHIN A 12-MONTH PERIOD.

323 (iv) A NUMBER OF CITATIONS AT SCOPE AND SEVERITY RATINGS D, E, F, G, H, I, J, K, L ON
 324 THE FEDERAL NURSING HOME REGULATION SCOPE AND SEVERITY MATRIX THAT EXCEEDS
 325 TWICE THE STATE AVERAGE.

326 (v) A CENTERS FOR MEDICARE AND MEDICAL SERVICES OR STATE MEDICAID AGENCY
 327 TERMINATION OR DECERTIFICATION ACTION.

(vi) AN OUTSTANDING DEBT TO THE DEPARTMENT (I.E., COST SETTLEMENT, CIVIL MONEY PENALTY [CMP] FINE, PROVIDER BED TAX, LICENSING FEES). THIS DOES NOT INCLUDE FINANCIAL ISSUES THAT ARE IN THE APPEAL PROCESS.

(vii) FAILURE TO COMPLY WITH A STATE CORRECTION NOTICE ORDER.

(viii) THE SANCTION OF THE APPLICANT, APPLICANT'S OWNER OR ANY CORPORATE OFFICER OF THE APPLICANT OR OWNER THAT RESULTS IN "EXCLUSION" FROM PARTICIPATION IN THE MEDICARE OR MEDICAID PROGRAM.

Section 7. Requirements for projects involving new construction or renovation

Sec. 7. (1) For projects involving new construction or renovation, an applicant shall demonstrate each of the following, as applicable:

(a) For projects involving the new construction of patient rooms, or room plan changes, the patient rooms shall be constructed or renovated to be consistent with the following minimum square feet of net usable area:

<u>Room Type</u>	<u>Net Usable Area Minimum Sq. Ft.</u>
One person	100
Two person	160
Three person	240
Four person	320

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

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

Section 8. Requirements for approval -- replacement beds

Sec. 8. An applicant proposing replacement 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) the project proposes to replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently located;

(b) the proposed licensed site is in the replacement zone, and

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

Section 9. Requirements for approval -- acquisition of a new nursing home or HLTCU

Sec. 9. An applicant proposing to acquire a new nursing home or HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home or HLTCU subject to the proposed acquisition is located if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition, and

(c) the project is limited solely to the acquisition of a nursing home or HLTCU with a valid license.

(D) AN APPLICANT WHO HAS, AT THE TIME OF APPLICATION, ANY OF THE DEFICIENCY CONDITIONS LISTED BELOW FOR THE NURSING HOME IDENTIFIED IN THIS APPLICATION AND FOR ALL NURSING HOMES OWNED AND OPERATED BY THE APPLICANT AND THE APPLICANT'S OWNER, SHALL BE INELIGIBLE FOR A CON UNLESS 12 MONTHS HAS PASSED SINCE THE

DEFICIENCY HAS BEEN REMEDIATED AND SUCH REMEDY CONFIRMED IN WRITING BY THE DEPARTMENT:

- (i) A STATE ENFORCEMENT ACTION INVOLVING LICENSE REVOCATION, A LIMITED OR TOTAL BAN ON ADMISSIONS, REDUCED LICENSE CAPACITY, SELECTIVE TRANSFER OF RESIDENTS, TEMPORARY MANAGER, OR RECEIVERSHIP.
- (ii) A CITATION FOR "IMMEDIATE JEOPARDY" UNDER THE FEDERAL REGULATORY REQUIREMENTS FOR NURSING HOMES.
- (iii) TWO (2) OR MORE CITATIONS WITH THE SAME FEDERAL REGULATORY GROUPING AT HARM LEVELS SCOPE AND SEVERITY RATINGS G, H, I ISSUED WITHIN A 12-MONTH PERIOD.
- (iv) A NUMBER OF CITATIONS AT SCOPE AND SEVERITY RATINGS D, E, F, G, H, I, J, K, L ON THE FEDERAL NURSING HOME REGULATION SCOPE AND SEVERITY MATRIX THAT EXCEEDS TWICE THE STATE AVERAGE.
- (v) A CENTERS FOR MEDICARE AND MEDICAL SERVICES OR STATE MEDICAID AGENCY TERMINATION OR DECERTIFICATION ACTION.
- (vi) AN OUTSTANDING DEBT TO THE DEPARTMENT (I.E., COST SETTLEMENT, CIVIL MONEY PENALTY [CMP] FINE, PROVIDER BED TAX, LICENSING FEES). THIS DOES NOT INCLUDE FINANCIAL ISSUES THAT ARE IN THE APPEAL PROCESS.
- (vii) FAILURE TO COMPLY WITH A STATE CORRECTION NOTICE ORDER.
- (viii) THE SANCTION OF THE APPLICANT, APPLICANT'S OWNER OR ANY CORPORATE OFFICER OF THE APPLICANT OR OWNER THAT RESULTS IN "EXCLUSION" FROM PARTICIPATION IN THE MEDICARE OR MEDICAID PROGRAM.

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), (b), and (c).

(a) A qualifying project will be awarded points, in accord with the schedule set forth below, based on the nursing home's/HLTCU's proposed percentage of the nursing home's/HLTCU's patient days of care to be reimbursed by Medicaid (calculated using total patient days for all existing and proposed beds at the facility) for the second 12 months of operation following project completion, and annually for at least seven years thereafter.

<u>Proposed Percentage of Medicaid Patient Days</u>	<u>Points Awarded</u>
0	0
1 - 19	1
20 - 39	2
40 - 59	3
60 - 100	4

(b) A qualifying project will be awarded points, in accord with the schedule set forth below, based on the nursing home's/HLTCU's proposed percentage, for the second 12 months of operation following project completion and annually for at least seven years thereafter, of all of the nursing home's/HLTCU's newly admitted patients (not including readmissions) that will be Medicaid recipients or Medicaid eligible recipients.

436		
437	Proposed	
438	Percentage of	
439	Medicaid	
440	<u>Admissions</u>	<u>Points</u>
441		<u>Awarded</u>
442	0	0
443	1 - 5	1
444	6 - 15	2
445	16 - 30	3
446	31 - 100	4
447		

448 (c) A qualifying project will be awarded Three points if, within six months of beginning operation
 449 and for at least seven years thereafter, 100 percent (100%) of the licensed nursing home beds at the
 450 facility (both existing and proposed) will be Medicaid certified.

451
 452 (3) A qualifying project will be awarded points, in accord with the schedule set forth below, based
 453 on its proposed participation in the Medicare program within six months of beginning operation and
 454 annually for at least seven years thereafter, including both physically conforming existing and proposed
 455 beds.

456		
457		<u>Points</u>
458	<u>Proposed Participation</u>	<u>Awarded</u>
459		
460	No Medicare certification of	0
461	any physically conforming	
462	existing and proposed beds.	
463		
464	Medicare certification of at least	1
465	one (1) bed but less than 100% of	
466	all physically conforming	
467	existing and proposed beds.	
468		
469	Medicare certification of 100% of	2
470	all physically conforming	
471	existing and proposed beds.	
472		

473 (4) A qualifying project will have points deducted based on the applicant's record of compliance with
 474 applicable federal and state safety and operating standards for any nursing home/HLTCU owned and/or
 475 operated by the applicant in Michigan. Points shall be deducted in accord with the schedule set forth below
 476 if, following the effective date of these standards, the records which are maintained by the Department
 477 document (a) any nonrenewal or revocation of license for cause and/or (b) nonrenewal or termination for
 478 cause of either Medicare or Medicaid certification of any Michigan nursing home/HLTCU owned and/or
 479 operated by the applicant.

480		
481	Nursing home/HLTCU	<u>Points</u>
482	<u>Compliance Action</u>	<u>Deducted</u>
483		
484	Nonrenewal or revocation of license	2
485		
486	Nonrenewal or termination of:	
487		
488	certification-Medicare	2
489	certification-Medicaid	2
490		

491 (5) A qualifying project will be awarded two points if, following project completion, the applicant will
 492 provide either directly or through contractual relationships, as part of its living or housing arrangements, a
 493 home for the aged, an adult foster care home, or independent housing located on the same site or in the
 494 same planning area.

495
 496 (6) A qualifying project will be awarded points based on the applicant's "Total proposed project cost
 497 per bed," in accord with the schedule set forth below, (where "A" represents "Average total proposed
 498 project cost per bed"):

500		Points
501	<u>Range of "Total proposed project cost per bed"</u>	<u>Awarded</u>
502		
503	0 to (A minus \$3000)	5
504	(A minus \$2999) to (A minus \$1000)	4
505	(A minus \$999) to (A plus \$1000)	3
506	(A plus \$1001) to (A plus \$5000)	2
507	(A plus \$5001) to (A plus \$11,000)	1
508	Above (A plus \$11,000)	0

509
 510 (7) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's
 511 cash" to be applied toward funding the "Total proposed project cost" in accord with the schedule set forth
 512 below:

514		Points
515	<u>Percentage "Applicant's Cash"</u>	<u>Awarded</u>
516		
517	Over 20 percent	5
518	15.1 to 20 percent	4
519	10.1 to 15 percent	3
520	5.1 to 10 percent	2
521	1.1 to 5 percent	1
522	0 to 1 percent	0

523
 524 (8) qualifying project will be awarded points for the following financing category:

526		Points
527	<u>Financing Category</u>	<u>Awarded</u>
528		
529	Interest only payments after	0
530	the period of construction	
531		
532	Payment of principal and interest	2
533	after the period of construction,	
534	according to an amortization schedule	

535 (9) No points will be awarded to an applicant under specific subsections of Section 10 if information
 536 presented in Section 10 is inconsistent with related information provided in other portions of the CON
 537 application.

538
 539 (10) The standards set forth in this section are assigned the weights listed below, with a weight of "1"
 540 being important, a weight of "2" being more important, and a weight of "3" being very important. The points
 541 awarded to an applicant in each of the subsections shall be multiplied by the applicable weight set forth
 542 below to determine the total number of points awarded to each applicant for each subsection.

543		
544	<u>Subsection</u>	<u>Weight</u>
545		
546	2(a)	3
547	2(b)	3
548	2(c)	3
549	3	1
550	4	2
551	5	1
552	6	2
553	7	2
554	8	1
555		

556 (11) The Department shall approve those qualifying projects which, taken together, do not exceed
557 the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan
558 Compiled Laws, and which have the highest number of points when the results of subsections (2) through
559 (10) are totaled. If two or more qualifying projects are determined to have an identical number of points,
560 then the Department shall approve those qualifying projects which, taken together, do not exceed the
561 need, as defined in Section 22225(1), in the order in which the applications were received by the
562 Department, based on the date and time stamp placed on the application for CON form (form T-150-G-
563 1.01 or any subsequent replacement form) by the Health Facilities Section, CON, when the application is
564 filed.

565
566 **Section 11. Project delivery requirements -- terms of approval for all applicants**
567

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

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

571 (b) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's
572 actual Medicaid participation within the time periods specified in these standards. Compliance with Section
573 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient
574 days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set
575 forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review
576 process. Compliance with Section 10(2)(b) shall be determined by comparing the actual number of
577 Medicaid recipients and Medicaid eligible recipients who were newly admitted, as a percentage of all
578 patients newly admitted to the nursing home/HLTCU, with the applicable schedule set forth in Section
579 10(2)(b) for which the applicant had been awarded points in the comparative review process. If any of the
580 following occurs, an applicant shall be required to be in compliance with the range in the schedule
581 immediately below the range for which points had been awarded in Section 10(2)(a) or (b), instead of the
582 range of points for which points had been awarded in the comparative review in order to be found in
583 compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all
584 nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12
585 months of operation after project completion and the most recent 12-month period for which data are
586 available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant
587 nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any
588 current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains
589 an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days
590 reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home
591 beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by
592 Medicaid for the most recent year for which data are available from the Michigan Department of Community
593 Health [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department
594 shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the
595 applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA provided to the Department
596 by the Michigan Department of Community Health.

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

601 (d) Compliance with applicable operating standards.

602 (e) Compliance with the following quality assurance standards:

603 (i) For projects involving replacement beds, the current patients of the facility/beds being replaced
 604 shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that
 605 those patients desire to transfer to the replacement facility/beds.

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

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

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

618
 619 (2) The agreements and assurances required by this section shall be in the form of a certification
 620 authorized by the governing body of the applicant or its authorized agent.

621

622 **Section 12. Department inventory of beds**

623

624 Sec. 12. The Department shall maintain, and provide on request, a listing of the Department Inventory
 625 of Beds for each planning area.

626

627 **Section 13. Wayne County planning areas**

628

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

631

632 Planning Area 84/Northwest Wayne

633

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

636

637 Planning area 85/Southwest Wayne

638

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

642

643 Planning area 86/Detroit

644

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

647

648 (2) A map showing the planning areas as listed in subsection (1) shall be available from the
 649 Department.

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Section 14. Health Service Areas

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

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

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

Sec. 15. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit Beds approved by the CON Commission on [March 9, 2004](#) ~~SEPTEMBER 14, 2004~~ and effective on [June 4, 2004](#) ~~DECEMBER 3, 2004~~.

(2) Projects reviewed under these standards, involving a change in bed capacity, shall be subject to comparative review except for replacement beds being replaced within the replacement zone.

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

APPENDIX A

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

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

- (i) age 0 - 64: 209 days of care
- (ii) age 65 - 74: 4,165 days of care
- (iii) age 75 - 84: 19,459 days of care
- (iv) age 85 +: 54,908 days of care

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

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

Planning Area	Bed Need	Department Inventory *	ADC Adjustment Factor
ALCONA	102	106	0.90
ALGER	70	106	0.90
ALLEGAN	474	565	0.95
ALPENA	203	208	0.95
ANTRIM	134	113	0.95
ARENAC	106	148	0.90
BARAGA	72	87	0.90
BARRY	262	252	0.95
BAY	638	668	0.95
BENZIE	93	102	0.90
BERRIEN	965	899	0.95
BRANCH	241	283	0.95
CALHOUN	805	850	0.95
CASS	272	222	0.95
CHARLEVOIX	134	134	0.95
CHEBOYGAN	154	162	0.95
CHIPPEWA	193	173	0.95
CLARE	173	200	0.95
CLINTON	251	251	0.95
CRAWFORD	85	160	0.90
DELTA	260	292	0.95
DICKINSON	230	256	0.95
EATON	431	444	0.95
EMMET	167	230	0.95
GENESEE	1,951	1,951	0.95
GLADWIN	150	180	0.95
GOGEBIC	195	221	0.95
GD. TRAVERSE	368	552	0.95
GRATIOT	272	556	0.95

* Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory Column do not reflect any data regarding applications for beds under appeal or pending a final Department decision.

APPENDIX B - continued

	Planning Area	Bed Need	Department Inventory *	ADC Adjustment Factor
772				
773				
774				
775				
776				
777				
778				
779				
780	HILLSDALE	262	262	0.95
781	HOUGHTON/KEWEENAW	314	335	0.95
782	HURON	278	313	0.95
783				
784	INGHAM	1,180	1,028	0.95
785	IONIA	275	248	0.95
786	IOSCO	193	243	0.95
787	IRON	150	149	0.95
788	ISABELLA	214	309	0.95
789				
790	JACKSON	828	847	0.95
791				
792	KALAMAZOO	1,120	1,154	0.95
793	KALKASKA	76	88	0.90
794	KENT	2,566	2,495	0.95
795				
796	LAKE	78	89	0.90
797	LAPEER	291	292	0.95
798	LEELANAU	111	110	0.90
799	LENAWEE	497	497	0.95
800	LIVINGSTON	421	475	0.95
801	LUCE	46	61	0.90
802				
803	MACKINAC	81	79	0.90
804	MACOMB	3,636	3,933	0.95
805	MANISTEE	170	221	0.95
806	MARQUETTE	361	441	0.95
807	MASON	197	202	0.95
808	MECOSTA	184	232	0.95
809	MENOMINEE	197	179	0.95
810	MIDLAND	338	414	0.95
811	MISSAUKEE	81	95	0.90
812	MONROE	619	595	0.95
813	MONTCALM	285	202	0.95
814	MONTMORENCY	89	104	0.90
815	MUSKEGON	904	917	0.95
816				
817	NEWAYGO	222	245	0.95
818				

819 * Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain
820 the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory
821 Column do not reflect any data regarding applications for beds under appeal or pending a final Department
822 decision.

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APPENDIX B - continued

Planning Area	Bed Need	Department Inventory *	ADC Adjustment Factor
OAKLAND	5,241	5,189	0.95
OCEANA	130	113	0.95
OGEMAW	131	233	0.95
ONTONAGON	76	110	0.90
OSCEOLA	118	54	0.95
OSCODA	69	90	0.90
OTSEGO	111	154	0.90
OTTAWA	874	796	0.95
PRESQUE ISLE	111	126	0.95
ROSCOMMON	171	179	0.95
SAGINAW	1,156	1,175	0.95
ST. CLAIR	789	722	0.95
ST. JOSEPH	355	369	0.95
SANILAC	269	287	0.95
SCHOOLCRAFT	72	75	0.90
SHIAWASSEE	350	327	0.95
TUSCOLA	292	293	0.95
VAN BUREN	411	424	0.95
WASHTENAW	1,032	1,285	0.95
WEXFORD	161	209	0.95
NW WAYNE	3,166	3,153	0.95
SW WAYNE	1,818	2,028	0.95
DETROIT	6,297	5,983	0.95

862 * Department Inventory shown is as of August 26, 2003. Applicants must contact the Department to obtain
863 the current number of beds in the Department Inventory of Beds. Note the figures in the Bed Inventory
864 Column do not reflect any data regarding applications for beds under appeal or pending a final Department
865 decision.

APPENDIX C866
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870**CON REVIEW STANDARDS**
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

871 Rural Michigan counties are as follows:

872

873	Alcona	Hillsdale	Ogemaw
874	Alger	Huron	Ontonagon
875	Antrim	Iosco	Osceola
876	Arenac	Iron	Oscoda
877	Baraga	Lake	Otsego
878	Charlevoix	Luce	Presque Isle
879	Cheboygan	Mackinac	Roscommon
880	Clare	Manistee	Sanilac
881	Crawford	Mason	Schoolcraft
882	Emmet	Montcalm	Tuscola
883	Gladwin	Montmorency	
884	Gogebic	Oceana	

885

886 Micropolitan statistical area Michigan counties are as follows:

887

888	Allegan	Gratiot	Mecosta
889	Alpena	Houghton	Menominee
890	Benzie	Isabella	Midland
891	Branch	Kalkaska	Missaukee
892	Chippewa	Keweenaw	St. Joseph
893	Delta	Leelanau	Shiawassee
894	Dickinson	Lenawee	Wexford
895	Grand Traverse	Marquette	

896

897 Metropolitan statistical area Michigan counties are as follows:

898

899	Barry	Ionia	Newaygo
900	Bay	Jackson	Oakland
901	Berrien	Kalamazoo	Ottawa
902	Calhoun	Kent	Saginaw
903	Cass	Lapeer	St. Clair
904	Clinton	Livingston	Van Buren
905	Eaton	Macomb	Washtenaw
906	Genesee	Monroe	Wayne
907	Ingham	Muskegon	

908

909 Source:

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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 and 6 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) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 *et seq.*

(b) "Infection control program," for purposes of Section 4(7), means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(c) "Licensed hospital" for purposes of Section 3(6) of this addendum, means either:

(i) a hospital licensed under Part 215 of the Code; or

(ii) a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(d) "Organized program," for purposes of sections 3(8) and 4(7), means a program operated by an applicant at the location at which the proposed nursing home beds will be operated that is consistent with the requirements of Section 4(7)(a) through (e), except Section 4(7)(c)(iv).

(e) "Private residence" for purposes of Section 3(6) of this addendum, means a setting other than:

(i) a licensed hospital; or

(ii) a nursing home including a nursing home or part of a nursing home approved pursuant to Section 3(6).

(f) "Ventilator-dependent patient," for purposes of sections 3(8) and 4(7), means a patient who does not require acute inpatient hospital services and either:

(i) requires mechanical ventilatory assistance for a minimum of 6 hours each day; or

(ii) is being weaned from ventilatory dependency.

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

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to Section 3 of this addendum.

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

972 **and nursing home populations**
973

974 Sec. 3. (1) A statewide pool of additional nursing home beds of 2.0% of the beds needed in the state
975 through application of the bed need methodology in the CON Review Standards for Nursing Home and
976 Hospital Long-term Care Unit Beds is established to better meet the needs of special population groups
977 within the long-term care and nursing home populations. Beds in the pool shall be allocated in accordance
978 with subsections 3(a), 4(a), 5(a), and 6(a).
979

980 (2) Increases in nursing home beds approved under this addendum for special population groups
981 shall not cause planning areas currently showing an unmet bed need to have that need reduced or
982 planning areas showing a current surplus of beds to have that surplus increased.
983

984 (3)(a) The CON Commission determines there is a need for beds for religious needs for specialized
985 services within the long-term care and nursing home populations and sets aside 302 beds from the total
986 statewide pool established in subsection (1) to address this need. Those needs are defined as being met
987 by those applications meeting the requirements of subsection (3)(b) or (c).

988 (b) An applicant proposing nursing home beds allocated under this subsection due to migration of
989 the patient population shall demonstrate with credible documentation to the satisfaction of the Department
990 each of the following:

991 (i) The applicant is currently licensed to operate a nursing home in Michigan and the application is
992 for replacement and/or relocation of an existing licensed facility.

993 (ii) The number of beds proposed for replacement must be equal to or less than the licensed
994 capacity of the applicant's existing nursing home on the date on which the CON application is filed.

995 (iii) The facility to be replaced does not meet licensing or certification standards for health facilities as
996 determined by the Department.

997 (iv) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a
998 recognized religious organization, denomination or federation as evidenced by documentation of its federal
999 tax exempt status as a religious corporation, fund, or foundation under Section 501(c)(3) of the United
1000 States Internal Revenue Code.

1001 (v) The applicant's patient population includes a majority of members of the religious organization or
1002 denomination represented by the sponsoring organization.

1003 (vi) The applicant's existing services and/or operations are tailored to meet certain special needs of a
1004 specific religion, denomination or order, including unique dietary requirements, or other unique religious
1005 needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.

1006 (vii) The replacement project responds to demographic changes, verifiable by the Department, which
1007 have decreased the representation of members of the religious organization or denomination in the
1008 planning area of the facility to be replaced and which have increased the representation of the members of
1009 the religious organization or denomination in the planning area of the replacement facility.

1010 (viii) An applicant proposing replacement beds shall not be required to be in compliance with Section
1011 8 (b) of the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, or any
1012 subsequent standard approved which requires the proposed new licensed site to be in the replacement
1013 zone.

1014 (c) An applicant proposing to add nursing home beds allocated under this subsection for a project
1015 other than described in subsection (b) shall demonstrate, with credible documentation to the satisfaction of
1016 the Department, each of the following:

1017 (i) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a
1018 recognized religious organization, denomination or federation as evidenced by documentation of its federal
1019 tax exempt status as a religious corporation, fund, or foundation under Section 501(c)(3) of the United
1020 States Internal Revenue Code.

1021 (ii) The applicant's proposed patient population includes a majority of members of the religious
1022 organization or denomination represented by the sponsoring organization.

1023 (iii) The applicant's proposed services and/or operations are tailored to meet certain special needs
1024 of a specific religion, denomination, or order, including unique dietary requirements, or other unique
1025 religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a
1026 secular setting.

1027 (4)(a) The CON Commission determines there is a need for beds for applications designed to
1028 determine the efficiency and effectiveness of specialized programs for the care and treatment of persons

1029 with Alzheimer's disease as compared to serving these needs in general nursing home unit(s) and
1030 designed to study the relationship between the needs of Alzheimer's disease patients and those of other
1031 non-specialized nursing home patients. The CON Commission sets aside 300 beds from the total
1032 statewide pool established in subsection (1) to address this need. Those needs are defined as being met
1033 by those applications meeting the requirements of subsection (4).

1034 (b) An applicant proposing to add nursing home beds allocated under this subsection shall
1035 demonstrate with credible documentation to the satisfaction of the Department each of the following:

1036 (i) The beds are part of a specialized program for Alzheimer's disease which will admit and treat
1037 only patients which require long-term nursing care and have been appropriately classified as a patient on
1038 the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a
1039 level 4 (when accompanied by continuous nursing needs), 5, or 6.

1040 (ii) The specialized program will participate in the state registry for Alzheimer's disease.

1041 (iii) The specialized program shall be attached or geographically adjacent to a licensed nursing home
1042 and be no larger than 20 beds in size.

1043 (iv) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the
1044 health facility, appropriate for unsupervised activity.

1045 (v) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area
1046 which is solely for the use of the Alzheimer's unit patients.

1047 (vi) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light
1048 reflections to promote visual and spatial orientation.

1049 (vii) Staff will be specially trained in Alzheimer's disease treatment.

1050 (viii) If the applicant has operated a specialized program and has demonstrated an occupancy rate of
1051 at least 97 percent in the Alzheimer's specialized unit(s) for the most recent, continuous 24-month period
1052 prior to submitting its application to the department, it may request up to an additional 20 beds but cannot
1053 exceed a total of 40 beds awarded from the statewide pool established in subsection (1).

1054 (A) The specialized unit(s) shall be no larger than 20 beds.

1055 (B) An applicant shall not be awarded more than a total of 40 beds.

1056 (c) Beds approved under this subsection shall not be converted to non-specialized non-Alzheimer's
1057 long-term care services without a CON for nursing home and hospital long-term care unit beds under the
1058 CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

1059
1060 (5)(a) The CON Commission determines there is a need for beds for the health needs for skilled
1061 nursing care services within the long-term care and nursing home populations and sets aside 257 beds
1062 from the total statewide pool established in subsection (1) to address this need. Those needs are defined
1063 as being met by those applications meeting the requirements of subsection (5).

1064 (b) An applicant proposing to add nursing home beds allocated under this subsection shall
1065 demonstrate with credible documentation to the satisfaction of the Department each of the following:

1066 (i) The planning area in which the beds will be located shall have a population density of less than
1067 28 individuals per square mile based on the 1990 U.S. Census figures as set forth in Appendix A.

1068 (ii) An application for beds from the special statewide pool of beds shall not be approved if any
1069 application for beds in that planning area has been approved from the special statewide pool of beds under
1070 Section 3(5).

1071 (iii) The average occupancy rate for the planning area in which the beds will be located shall have
1072 been at least 95% for each of the three most recent years for which the Department has either: annual
1073 survey data; or data reported to the Department for purposes of compiling the "Staffing/Bed Utilization
1074 Ratios Report," whichever is the most recent data available. In determining the average occupancy rate for
1075 the planning area, the first six months of occupancy for any newly opened facility or newly opened part of a
1076 facility in that period shall be excluded.

1077 (iv) An application shall not be approved if it proposes more than 40 beds.

1078 (v) All beds approved pursuant to this subsection shall be dually certified for Medicare and
1079 Medicaid.

1080
1081 (6)(a) The CON Commission determines there is a need for beds for patients requiring both hospice
1082 and long-term nursing care services within the long-term care and nursing home populations and sets
1083 aside 100 beds from the total statewide pool established in subsection (1) to address this need. Those
1084 needs are defined as being met by those applications meeting the requirements of subsection (6).

- 1085 (b) An applicant proposing to add nursing home beds allocated under this subsection shall
 1086 demonstrate, with credible documentation to the satisfaction of the department, each of the following:
- 1087 (i) An applicant shall be a hospice certified by Medicare pursuant to the Code of Federal
 1088 Regulations, Title 42, Chapter IV, Subpart B (Medicare programs), Part 418 and shall have been a
 1089 Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to
 1090 the Department.
- 1091 (ii) An applicant shall demonstrate that, during the most recent 12 month period prior to the date an
 1092 application is submitted to the Department for which verifiable data are available to the Department, at least
 1093 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were
 1094 provided in a private residence.
- 1095 (iii) An application shall propose 30 beds or less.
- 1096 (iv) An applicant for beds from the special statewide pool of beds shall not be approved if any
 1097 application for beds in that same planning area has been approved from the special statewide pool of beds
 1098 under Section 3(6).
- 1099 (v) An applicant shall submit, at the time an application is submitted to the Department, a study
 1100 which documents, to the satisfaction of the Department, that both (A) and (B) have been contacted
 1101 regarding the availability of either beds or space for acquisition (whether through purchase, lease or other
 1102 comparable arrangement) for use by the proposed project, and that either: (1) beds or space are not
 1103 available for acquisition; or (2) if beds or space are available for acquisition, the capital costs of developing
 1104 the beds or space in the acquired space for use by the proposed project are higher than the applicant's
 1105 proposed project costs.
- 1106 (A) Each licensed hospital in the planning area.
- 1107 (B) Each licensed nursing home or hospital long-term care unit in the planning area.
- 1108 If an applicant does not receive a response from (A) or (B) within 30 days of the date of contact, an
 1109 applicant shall demonstrate that contact was made by 1 certified mail return receipt for each organization
 1110 contacted. The requirements of this subdivision shall not apply to nursing homes or hospital long-term care
 1111 units that either:
- 1112 (1) Have not been cited by the Department's Division of Licensing and Certification for 1 or more
 1113 level a deficiencies during the 12 months prior to the date an application is submitted to the Department.
- 1114 (2) Have been granted, by the Department, a waiver of 1 or more physical plant licensure
 1115 requirements.
- 1116
- 1117 (7)(a) The number of beds set aside from the total statewide pool established in subsection (1) for a
 1118 special population group shall be reduced if there has been no CON activity for that special population
 1119 group during at least 6 consecutive application periods.
- 1120 (b) The number of beds in a special population group shall be reduced to the total number of beds
 1121 for which a valid CON has been issued for that special population group.
- 1122 (c) The number of beds reduced from a special population group pursuant to this subsection shall
 1123 revert to the total statewide pool established in subsection (1).
- 1124 (d) The Department shall notify the Commission of the date when action to reduce the number of
 1125 beds set aside for a special population group has become effective and shall identify the number of beds
 1126 that reverted to the total statewide pool established in subsection (1).
- 1127 (e) For purposes of this subsection, "application period" means the period of time from one
 1128 designated application date to the next subsequent designated application date.
- 1129 (f) For purposes of this subsection, "CON activity" means one or more of the following:
- 1130 (i) CON applications for beds for a special population group have been submitted to the Department
 1131 for which either a proposed or final decision has not yet been issued by the Department.
- 1132 (ii) Administrative hearings or appeals to court of decisions issued on CON applications for beds for
 1133 a special population group are pending resolution.
- 1134 (iii) An approved CON for beds for each special population group has expired for lack of appropriate
 1135 action by an applicant to implement an approved CON.
- 1136
- 1137 (8)(a) The CON Commission determines there is a need for beds for ventilator-dependent patients
 1138 within the long-term care and nursing home populations and sets aside 0 beds from the total statewide pool
 1139 established in subsection (1) to address this need. Those needs are defined as being met by those
 1140 applications meeting the requirements of subsection (8). By setting aside these beds from the total
 1141 statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds

1142 pursuant to this subsection and does not preclude the care of ventilator-dependent patients in units of
 1143 hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with
 1144 applicable statutory or certification requirements.

1145 (b) An applicant proposing to add nursing home beds allocated under this subsection shall
 1146 demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

1147 (i) An applicant has an organized program for caring for ventilator-dependent patients in licensed
 1148 hospital beds, and has been recognized by the Department or the Michigan Department of Social Services
 1149 as having provided an organized program for caring for ventilator-dependent patients for at least 30
 1150 continuous months prior to the date on which an application under this subsection is submitted to the
 1151 Department.

1152 (ii) An application proposes no more than 15 beds that will be licensed as nursing home beds under
 1153 Part 217 of the Code.

1154 (iii) The proposed unit will be located in a hospital licensed under Part 215 of the Code.

1155 (iv) An applicant for beds from this special statewide pool of beds shall not be approved if any
 1156 application for beds in the same county has been approved from the special statewide pool of beds under
 1157 Section 3(8).

1158 (v) The proposed unit will serve only ventilator-dependent patients.

1159 (vi) An applicant shall delicense a number of licensed hospital beds equal to or than greater than the
 1160 number of beds proposed pursuant to this subsection.

1161 (vii) All beds approved pursuant to this subsection shall be dually certified for Medicare and
 1162 Medicaid.

1163
 1164 **Section 4. Project delivery requirements -- terms of approval for all applicants seeking approval**
 1165 **under Section 3**

1166
 1167 Sec. 4. (1) An applicant shall agree that if approved, the services shall be delivered in compliance
 1168 with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-
 1169 term Care Unit Beds.

1170
 1171 (2) In addition to the terms of approval required by the CON Review Standards for Nursing Home
 1172 and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(3)(b) shall agree that, if
 1173 approved, the services provided by the specialized long-term care beds shall be delivered in compliance
 1174 with the following terms of CON approval:

1175 (a) The applicant shall submit a resolution of its governing body certifying that it shall cease
 1176 operations as a licensed health care facility at the existing licensed site, and that the license of the existing
 1177 site which is replaced under Section 3(3) shall be surrendered to the Department concurrently with the
 1178 licensure of a replacement facility approved under Section 3(3)(b).

1179 (b) The applicant shall document, at the end of the third year following initiation of beds approved
 1180 pursuant to Section 3(3)(b), an annual average occupancy rate of 95 percent or more. If this occupancy
 1181 rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent
 1182 occupancy based upon its average daily census for the third full year of operation.

1183 (c) When opening, the replacement facility shall admit the current patients of the facility being
 1184 replaced to the extent those patients desire to transfer to the replacement facility.

1185
 1186 (3) In addition to the terms of approval required by the CON Review Standards for Nursing Home
 1187 and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(3)(c) shall agree that, if
 1188 approved, the services provided by the specialized long-term care beds shall be delivered in compliance
 1189 with the following term of CON approval:

1190 (a) The applicant shall document, at the end of the third year following initiation of beds approved
 1191 pursuant to Section 3(3)(c) an annual average occupancy rate of 95 percent or more. If this occupancy
 1192 rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent
 1193 occupancy based upon its average daily census for the third full year of operation.

1194
 1195 (4) In addition to the terms of approval required by the CON Review Standards for Nursing Home
 1196 and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(4) shall agree that if
 1197 approved:

1198 (a) The services provided by the specialized Alzheimer's disease beds shall be delivered in
1199 compliance with the requirements for approval in subsections 3(4)(a) and (b); and
1200 (b) All beds approved pursuant to that subsection shall be certified for Medicaid.

1201
1202 (5) In addition to the terms of approval required by the CON Review Standards for Nursing Home
1203 and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(5) shall agree that if
1204 approved, all beds approved pursuant to that subsection shall be dually certified for Medicare and
1205 Medicaid.

1206
1207 (6) In addition to the terms of approval required by the CON Review Standards for Nursing Home
1208 and Hospital Long-term Care Unit Beds, an applicant for beds under Section 3(6) shall agree that, if
1209 approved, all beds approved pursuant to that subsection shall be operated in accordance with the following
1210 CON terms of approval.

1211 (a) An applicant shall maintain Medicare certification of the hospice program and shall establish and
1212 maintain the ability to provide, either directly or through contractual arrangements, hospice services as
1213 outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.

1214 (b) The proposed project shall be designed to promote a home-like atmosphere that includes
1215 accommodations for family members to have overnight stays and participate in family meals at the
1216 applicant facility.

1217 (c) An applicant approved for nursing home beds pursuant to Section 3(6) shall not refuse to admit a
1218 patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.

1219 (d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or
1220 have AIDS related complex in nursing home beds approved pursuant to Section 3(6).

1221 (e) An applicant shall make accommodations to serve children and adolescents as well as adults in
1222 nursing home beds approved pursuant to Section 3(6).

1223 (f) Nursing home beds approved pursuant to Section 3(6) shall only be used to provide services to
1224 individuals suffering from a disease or condition with a terminal prognosis in accordance with Section
1225 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

1226 (g) An applicant shall agree that the nursing home beds approved pursuant to Section 3(6) of these
1227 standards shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code,
1228 being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and
1229 approved pursuant to applicable CON review standards.

1230 (h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section
1231 333.21401 et seq. of the Michigan Compiled Laws.

1232 (i) An applicant shall agree that at least 64% of the total number of hospice days of care provided
1233 by the applicant hospice to all of its clients will be provided in a private residence.

1234 (j) An applicant shall annually provide data to determine the efficiency and effectiveness of
1235 providing, in a nursing home or hospital long-term care unit, room and board services to hospice clients
1236 that would otherwise be treated in a private residence if a capable primary caregiver was available. An
1237 applicant shall, at a minimum, provide data to the Department on a calendar year basis for each of the
1238 following:

1239 (i) The number of hospice patients and associated days of care for general inpatient and respite
1240 inpatient hospice care;

1241 (ii) The number of hospice patients and associated days of care for hospice routine and continuous
1242 home care not provided in a nursing home or hospital long-term care unit; and

1243 (iii) The number of hospice patients and associated days of care for hospice room and board in a
1244 nursing home.

1245 (iv) The total number of hospice clients and associated days of care served by the applicant hospice
1246 which shall be the sum of subdivisions (i), (ii), and (iii).

1247 These data shall be considered when revisions to these standards are considered. The Department shall
1248 annually report to the Commission a summary of the data collected pursuant to this requirement. At a
1249 minimum, the summary shall report the occupancy rate and average length of stay for each applicant
1250 approved pursuant to Section 3(6) of this addendum.

1251 (7) In addition to the terms of approval required by the CON review standards for nursing home and
1252 hospital long-term care unit beds, an applicant for beds under Section 3(8) shall agree that, if approved, all
1253 beds approved pursuant to that subsection shall be operated in accordance with the following CON terms
1254 of approval.

- 1255 (a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been
1256 trained in the care and treatment of ventilator-dependent patients and includes at least the following:
1257 (i) a medical director with specialized knowledge, training, and skills in the care of ventilator-
1258 dependent patients.
1259 (ii) a program director that is a registered nurse.
1260 (b) An applicant shall make provisions, either directly or through contractual arrangements, for at
1261 least the following services:
1262 (i) respiratory therapy.
1263 (ii) occupational and physical therapy.
1264 (iii) psychological services.
1265 (iv) family and patient teaching activities.
1266 (c) An applicant shall establish and maintain written policies and procedures for each of the
1267 following:
1268 (i) patient admission criteria that describe minimum and maximum characteristics for patients
1269 appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the
1270 amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary
1271 services.
1272 (ii) The transfer of patients requiring care at other health care facilities.
1273 (iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment
1274 plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.
1275 (iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code,
1276 being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.
1277 (v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.
1278 (d) An applicant shall establish and maintain an organized infection control program that has written
1279 policies for each of the following:
1280 (i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and
1281 frequency of tube changes.
1282 (ii) placement and care of urinary catheters.
1283 (iii) care and use of thermometers.
1284 (iv) care and use of tracheostomy devices.
1285 (v) employee personal hygiene.
1286 (vi) aseptic technique.
1287 (vii) care and use of respiratory therapy and related equipment.
1288 (viii) isolation techniques and procedures.
1289 (e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least
1290 a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and
1291 representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This
1292 subsection does not require a separate committee, if an applicant organization has a standing infection
1293 control committee and that committee's charge is amended to include a specific focus on the ventilator-
1294 dependent unit.
1295 (f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the
1296 immediate vicinity of the unit.
1297 (g) An applicant shall agree that all beds approved pursuant to Section 3(8) will be dually certified for
1298 Medicare and Medicaid reimbursement.
1299 (h) An applicant approved for beds pursuant to Section 3(8) shall agree that the beds will not be
1300 used to service individuals that are not ventilator-dependent unless a separate CON is requested and
1301 approved by the Department pursuant to applicable CON review standards.
1302 (i) An applicant approved for beds pursuant to Section 3(8) shall provide data to the Department
1303 that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a
1304 hospital.
1305

1306 **Section 5. Comparative reviews, effect on prior CON review standards**
1307

1308 Sec. 5. (1) Projects proposed under Section 3(3) shall be considered a distinct category and shall be
1309 subject to comparative review on a statewide basis.

1310
1311 (2) Projects proposed under Section 3(4) shall be considered a distinct category and shall be subject
1312 to comparative review on a statewide basis.

1313
1314 (3) Projects proposed under Section 3(5) shall be considered a distinct category and shall be subject
1315 to comparative review on a statewide basis.

1316
1317 (4) Projects proposed under Section 3(6) shall be considered a distinct category and shall be subject
1318 to comparative review on a statewide basis.

1319
1320 (5) Projects proposed under section 3(8) shall be considered a distinct category and shall be subject
1321 to comparative review on a statewide basis.

1322
1323 (6) These CON review standards supercede and replace the CON Review Standards for Nursing
1324 Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the
1325 Commission on March 9, 2004 and effective on June 4, 2004.

1326 **Section 6. Acquisition of nursing home or hospital long-term care unit beds approved pursuant to**
1327 **this addendum.**
1328

1329
1330 Sec. 6. (1) An applicant proposing to acquire nursing home or hospital long-term care unit beds
1331 approved pursuant to Section 3(3)(b) or (c) of this addendum shall demonstrate that it is in
1332 compliance with the requirements of Section 3(3)(b)(iv), (v) and (vi) of this addendum.

1333
1334 (2) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved
1335 pursuant to Section 3(4) of this addendum shall demonstrate that it is in compliance with the requirements
1336 of Section 3(4)(b)(i), (ii), (iii), (iv), (v), (vi), (vii) and (viii) of this addendum.

1337
1338 (3) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved
1339 pursuant to Section 3(6) of this addendum shall demonstrate that it is in compliance with the requirements
1340 of Section 3(6)(b)(i) and (ii) of this addendum.

1341
1342 (4) An applicant proposing to acquire beds approved pursuant to Section 3(8) of this Addendum
1343 shall demonstrate that it is in compliance with the requirements of Section 3(8) of this Addendum.

1344
1345 (5) An applicant proposing to acquire nursing home or hospital long-term care unit beds approved
1346 pursuant to this addendum shall agree to all applicable project delivery requirements set forth in Section 4
1347 of this addendum.

APPENDIX A

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FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS**

1354 Michigan nursing home planning areas with a population density of less than 28 individuals per square mile
1355 based on 1990 U.S. Census figures.

1356		Population Density
1357	<u>Planning Area</u>	<u>per Square Mile</u>
1360	Luce	6.4
1361	Ontonagon	6.8
1362	Schoolcraft	7.1
1363	Baraga	8.8
1364	Alger	9.8
1365	Mackinac	10.4
1366	Iron	11.3
1367	Oscoda	13.8
1368	Alcona	14.9
1369	Lake	15.1
1370	Montmorency	16.2
1371	Gogebic	16.3
1372	Presque Isle	21.0
1373	Missaukee	21.5
1374	Chippewa	21.8
1375	Crawford	21.9
1376	Menominee	23.8
1377	Houghton/Keweenaw	23.9
1378	Kalkaska	24.0

1379
1380
1381 **Source:** Michigan Department of Management and Budget and
1382 the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR NEW DESIGN MODEL PILOT PROGRAM

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds and provides for the establishment of a statewide pilot new design model program.

(2) Except as provided in sections 3 and 4 of this addendum, this addendum supplements, and does not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds.

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

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

(a) "New design model" means a new nursing home or hospital long-term care unit constructed, renovated, or replaced under the requirements set forth in this addendum.

(b) "Replacement beds" means the applicant proposes to replace an equal or lesser number of beds than currently licensed to the applicant.

(c) "Licensed site" means the geographic location specified on a nursing home or hospital long-term care unit license.

Section 2. Requirements for approval – purpose of applying for pilot program for a new construction, or replacement/renovation of an existing facility

Sec. 2. A statewide pilot program is established to study the potential benefit of new designs in the new construction, renovation, and/or replacement of existing nursing home and hospital long term-care facilities throughout Michigan. Pilot projects under this addendum shall be new construction, renovation, or replacement projects within the current bed need methodology that conform to the pilot model construction requirements in Section 3.

Section 3. Statewide pilot - new design model for new construction or replacement/renovation facility components

Sec. 3. (1) The pilot will be limited to new construction, renovation, and/or replacement facilities for 4 years, starting on DECEMBER 3, 2004, the effective date of this addendum. Applications for a pilot project will not be subject to comparative review.

(2) Projects in the pilot new design model must result in no more than 100 beds per new design model and meet the following design standards:

(a) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled "Minimum Design Standards for Health Care Facilities in Michigan" dated March 1998 and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

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

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

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

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

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

1440 (c) All new construction, renovation, or replacement facilities approved under this pilot shall comply
 1441 with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

1442 (d) The Department may waive construction requirements for pilot projects if authorized by law.
 1443

1444 (3) Pilot projects shall include at least 80% single occupancy resident rooms with an adjoining
 1445 bathroom serving no more than two residents in both the central support inpatient facility and any
 1446 supported small resident housing units. If the pilot project is for replacement/renovation of an existing
 1447 facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility
 1448 shall not exceed double occupancy.
 1449

1450 (4)(a) The number of beds needed in a planning area as determined by the current bed need
 1451 methodology will not be changed for this pilot program.

1452 (b) Projects involving the replacement of existing beds must replace the beds at a location in the
 1453 replacement zone unless the applicant demonstrates that all of the following are met:

1454 (i) The proposed licensed site for the replacement beds is in the same planning area, and not within
 1455 a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including
 1456 approved projects) within five calendar years prior to the effective date of this addendum,

1457 (ii) the applicant shall provide a signed affidavit or resolution from its governing body or authorized
 1458 agent stating that the proposed licensed site will continue to provide service to the same market, and

1459 (iii) the current patients of the facility/beds being replaced shall be admitted to the replacement beds
 1460 when the replacement beds are licensed, to the extent that those patients desire to transfer to the
 1461 replacement facility/beds.
 1462

1463 (5) An approved pilot project may involve replacement of a portion of the beds of an existing facility
 1464 at a geographic location within the replacement zone that is not physically connected to the current
 1465 licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a
 1466 separate license shall be issued to the facility at the new location.
 1467

1468 (6) The applicant, at the time the application is submitted to the Department, shall demonstrate an
 1469 agreement to evaluate the new design cooperatively with an appropriate evaluation agent that has been
 1470 approved by the Office of Services to the Aging (OSA), MDCH and Medical Services Administration (MSA),
 1471 MDCH. The evaluation will include but is not limited to the following areas: (a) quality of care and quality
 1472 indicators, (b) client and/or family satisfaction, (c) utilization of drugs, (d) staff recruitment and retention, (e)
 1473 annual survey reports including complaints, and (f) the impact on capital and operating costs. The
 1474 evaluation may be expanded to other areas as needed to determine the impact of the new design on
 1475 delivery of care and quality of life.
 1476

1477 (7) The applicant shall demonstrate, at the time the application is submitted to the Department, all of
 1478 the following:

1479 (a) The nursing home or hospital long-term care unit has not been cited by the Department for 1 or
 1480 more Standard Quality of Care (SQOC) citations, as defined in the federal regulations, during the 12
 1481 months prior to the date an application is submitted to the Department.

1482 (b) The nursing home or hospital long-term care unit's parent or any subsidiary has taken actions
 1483 acceptable to the Department to correct, improve, or remedy any condition or concern that resulted in a
 1484 SQOC citation issued over the past 12-month period in any nursing home or hospital long-term care unit
 1485 under its parent or any subsidiary.
 1486

1487 **Section 4. Pilot project - terms of approval for all applicants seeking approval under Section 3**

1488
 1489 Sec. 4. (1) An applicant shall agree that if approved, the services shall be delivered in compliance
 1490 with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-
 1491 Term Care Unit Beds.
 1492

1493 (2) In addition to the terms of approval required by the CON Review Standards for nursing Home
 1494 and Hospital Long-Term Care Unit Beds, an applicant for beds under this addendum shall agree that, if
 1495 approved, all beds approved pursuant to this addendum shall be dually certified for Medicare and Medicaid.
 1496 The inability to obtain Medicaid certification of nursing home beds due to the aggregate state-wide limit on

1497 the maximum number of Medicaid-certified nursing home beds in Michigan shall not constitute grounds for
1498 revocation of the CON if the applicant furnishes to the Department, within one year from the date of CON
1499 approval, proof of Medicaid certification or denial of Medicaid certification (based upon the state-wide limit)
1500 along with a signed affidavit stating the willingness to certify 100% of the beds subject to CON approval
1501 under this pilot program when accepted by Medicaid.
1502

1503 **Section 5. Acquisition of nursing home or hospital long-term care unit beds approved pursuant to**
1504 **this addendum.**
1505

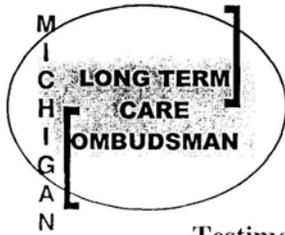
1506 Sec. 5. (1) An applicant proposing to acquire a nursing home or hospital long-term care facility
1507 that has been approved as a pilot project pursuant to this addendum shall demonstrate that it is, and will
1508 continue to be, in compliance with the requirements of this addendum as a condition of approval.
1509

1510 (2) An applicant proposing to acquire a nursing home or hospital long-term care facility that has
1511 been approved as a pilot project pursuant to this addendum shall agree to all applicable project delivery
1512 requirements set forth in Section 4 of this addendum, as a condition of approval.
1513

1514 (3) An applicant proposing to acquire a nursing home or hospital long-term care facility that has
1515 been approved as a pilot project pursuant to this addendum must demonstrate, at the time the application
1516 is submitted to the Department, all of the following:

1517 (a) The applicant or any nursing home or hospital long-term care unit owned or operated by the
1518 applicant has not been cited by the Department for 1 or more Substandard Quality of Care (SQOC)
1519 citations, as defined in the federal regulations, during the 12 months prior to the date an application is
1520 submitted to the Department.

1521 (b) The applicant's parent or any subsidiary has taken actions acceptable to the Department to
1522 correct, improve, or remedy any condition or concern that resulted in a SQOC citation issued over the past
1523 12-month period in any nursing home or hospital long-term care unit under its parent or any subsidiary.



**Testimony on CON HLTCU/Nursing Home Standards
Proposed Changes, June 21, 2006, By Sarah Slocum**

Members of the Certificate of Need Commission (CON), my name is Sarah Slocum and I am the Michigan State Long Term Care Ombudsman. I thank you for the opportunity to speak with you today about some important proposed changes to the CON standards for Hospital Long Term Care Units and Nursing Homes in Michigan.

The Long Term Care Ombudsman Program serves as an advocate for consumers in long term care, and as such we are always looking for ways to improve the quality of available settings and services. I am here supporting the proposed changes before you today because they will do a number of positive things related to quality in long term care facilities.

First I commend and thank Commissioner Brad Cory for his leadership and work in developing these proposed standards. He and the department brought together a group of interested people, representing the various constituencies affected by CON standards to create a consensus proposal for your consideration.

Second, the proposed language is an important step forward in requiring high quality from nursing homes, corporations, and organizations that want to buy or build nursing homes. The proposal would encourage high performing nursing home owners by allowing them to expand, while requiring struggling providers to first establish at least a one year track record of quality care before any new CON applications could be approved for them.

Third, the proposal is consistent with the Governor's Medicaid Long Term Care Task Force recommendations on improving quality in long term care through a variety of approaches. This positive approach of requiring certain quality measures be reached before CONs are granted supports the task force vision of quality improvement.

Finally, the proposal requires entire corporations or organizations to meet minimum standards before CONs can be granted. This is an important element of the proposal, and requires owners to pay attention to current problems, before building or acquiring more nursing home beds.

I applaud the Certificate of Need Commission for considering these proposed changes, and I urge you to adopt this proposal to create lasting improvement in CON standards and nursing facility quality.

State Long Term Care Ombudsman, Sarah Slocum, 7109 W. Saginaw, P.O. Box 30676, Lansing, MI 48909. Telephone 517/335-1560, Fax 517/373-4092



TO: Michigan Certificate of Need Commission

FROM: Andrew Farmer, Associate State Director
Health & Supportive Services
AARP Michigan

RE: Proposed Department Policy on Nursing Home and Hospital Long Term Care Unit
Beds Standards Modifications

DATE: June 21, 2006

AARP Michigan is this Association's state organization, representing its 1.5 million members who live, work and retire here. Our Social Impact Agenda is broadly based to encompass many health and economic issues, and quality of health care, especially quality in long term care, are priorities meeting at the cross-roads of both health and economic issues which we and our members care passionately about.

The Certificate of Need Process has been a well-established tool for containing the costs by managing the capacity of our health care delivery system. With the proposed policy modifications before you, the Michigan Department of Community Health takes the powerful leverage of the Commission and harnesses it to leverage new quality outcomes in nursing home services.

In short, nursing home providers with positive public track records of quality of care and quality of life delivery to our state's most frail elders and persons with disabilities are moved to the front of the line and rewarded with consideration of CoN applications to change their capacities, while those providers with poor track records become ineligible to make such applications. In short, only proven, successful nursing home operators have the chance to expand their operations. Unsuccessful ones are appropriately penalized and denied the ability to expand poor services in this same market.

The Department's proposed modifications are positive, innovative and appropriate – and a major step forward in improving the quality of nursing home services for the people of Michigan. AARP Michigan urges this Commission's adoption of these modifications and we thank you for this opportunity to express our strong support of them.

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toll-free 1-877-434-7598 TTY | Erik D. Olsen, President | William D. Novelli, Chief Executive Officer | www.aarp.org/mi

Reginald Carter

**Certificate of Need Commission
Conditional Approvals for Nursing Facilities
June 21, 2006**

Thank you for allowing the Health Care Association of Michigan to bring the issue of conditions included on CON approvals for nursing facilities. The Department of Community Health has been issuing CON approval letters with specific conditions since late last year that relate to the OBRA survey process and ties related organizations to the applicant.

HCAM is questioning the authority of the department staff under CON Rule 325.9301 (3) to issue these types of conditions without Commission approval. We understand that this rule does provide for conditions to be included in approvals of projects subject to CON. However, we are concerned the conditions go beyond the scope permitted in the rules in that they deal with the nursing facility survey and certification requirements and contain clauses connecting related entities.

HCAM Legal Counsel has provided the following interpretation of the laws and rules governing CON approvals. We would like to provide the Commission with that legal interpretation. HCAM Legal Counsel wrote:

The Department of Community Health has recently begun to place in Certificate of Need ("CON") approval letters, certain conditions relating not only to applicant but to the applicant's owner and to any other facility with which the owner may be involved. These are severe restrictions which make it virtuously impossible to meet the conditions for Certificate of Need, thus in effect rendering the Certificate of Need program a nullity. More specifically, MDCH has begun to issue CON approval letters conditioned upon other facilities in the chain to which the applicant will belong, remaining in substantial compliance with all OBRA requirements. This is regardless of the fact that the CON applicant may be a completely separate and distinct legal entity (i.e., corporation, L.L.C., or partnership) from every other licensed facility in the chain.

These conditions are in violation of existing law and regulation in that the Department has exceeded any powers granted to it under the Public Health Code. It is an elemental principle of law that administrative agencies do not have any power except such power as is expressly given to them under the applicable statute creating them or under the Michigan Constitution. Thus, MDCH has no power to extend the provisions of the statute to those who are not applicants for CON purposes. The Public Health Code provides that no person shall operate a nursing home without first obtaining a Certificate of Need. Under the law a "person" includes a legal entity such as a corporation, L.L.C., etc. The statute therefore clearly identifies each CON applicant as a distinct legal entity and cannot be read to mean that all individuals or entities in any way related to the applicant are also considered to be the applicant for CON approval purposes.

CON Commission June 21, 2006
Statement By: Health Care Association of Michigan
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The statute sets forth the conditions under which a Certificate of Need may be issued to applicant. One must note that the applicant is the specific legal entity or individual seeking to obtain a Certificate of Need, and no other person.

The only reference to conditions in the Public Health Code is in sections 333.22237 and 333.22239. These conditions are not the conditions that the Department is currently attempting to impose in its Certificate of Need approvals. MDCH's attempt to impose conditions beyond those expressly permitted under law, exceeds MDCH's authority and is in violation of law and the Constitution.

MDCH has also promulgated rules under which it intends to conduct the Certificate of Need process, under the powers granted by statute. In that set of rules the "applicant" is defined clearly as the "person" (i.e., individual, corporation or other legal entity) applying for Certificate of Need. The remainder of the rules sets forth a series of requirements for the applicant. At no time do the rules allow or authorize the Department to set forth other conditions such as the conditions it currently is attempting to impose. These new conditions relate not only to the applicant but to other facilities which may be owned by the applicant's owner or any corporate officer of the applicant or owner. The department seeks to ignore the legal entity (in direct violation of the definition of "applicant" and "person" under the Code) so as to extend its authority to not only the applicant but the applicant's owner or any corporate officer of the applicant or owner. Once again this action is beyond the authority of the agency.

Finally, the only place where one can find conditions similar to the new conditions MDCH seeks to impose, are in the standards for comparative review of applications for Certificate of Need which the CON Commission established under the statute. There is nothing in those standards that allow the conditions as set forth in the Agency's current conditions for the usual Certificate of Need. In that section one of the standards which is to be applied in evaluating which one of a number of applicants should get a Certificate of Needs, includes a discussion of a point system, and one of the points in the system used by the review board is that a qualifying project will have points deducted based on the specific applicant's record of compliance with applicable federal and state safety and operating standards for any nursing home owned and/or operated by the applicant in Michigan. Points shall be deducted in accordance with the schedule set forth below. Since the compliance with certification standards applies solely to the applicant, then under well-established principles of statutory construction it is clear that the CON Commission meant such criteria to apply solely in the comparative review context, and only to the applicant itself and not to "persons" other than the applicant.

It is also of note that MDCH has the power to enforce the state and federal licensure/certification requirements through an elaborate and well-established enforcement process, set forth in federal statute and federal and state regulation. The Department is clearly overstepping its authority by seeking to impose

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conditions such as these without utilizing its promulgated enforcement procedure (which of course only applies to a specific licensee and cannot use one licensee's citations to negatively affect another licensee).

In summary, since neither the legislature nor the Michigan Constitution gave any authority to the Department to limit the issuance of Certificates of Need to the conditions that they are currently employing, it must follow such conditions are beyond the power of the Department to mandate as a condition precedent to issuance of a certificate.

HCAM requests that the CON Commission take this under advisement and based on that advice review all CON approvals issued with these conditions. Since these involve ongoing projects a quick response would serve everyone.

Thank you for considering our request.

Attachment: Conditions

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Statement By: Health Care Association of Michigan
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**DRAFT – REVISED 4-3-06
CON CONDITIONS**

1. This approval is contingent upon the applicant and applicant's owner's correction of federal deficiency conditions listed below, compliance with other licensure and certification conditions listed for those conditions present as of the date of this conditional approval, for the nursing home identified in this application and for all nursing homes owned or operated by the applicant and applicant's owner. Non-compliance with the requirements of this approval will result in action in accordance with Section 22247 of the Public Health Code:
 - a. A state enforcement action involving license revocation, a limited or total Ban on Admissions, reduced license capacity, selective transfer of residents, or receivership.
 - b. A citation for "Immediate Jeopardy" under the federal regulatory requirements for nursing homes.
 - c. Two or more citations within the same federal regulatory grouping at harm levels scope and severity ratings G,H, I issued within a 12 month period.
 - d. A number of citations at scope and severity ratings D,E, F, G, H, I, J, K, L on the federal nursing home regulation scope and severity matrix that exceeds twice the state average in the year of approval.
 - e. A Centers for Medicare and Medicaid Services or State Medicaid Agency termination or decertification action.
 - f. An outstanding debt to MDCH (i.e., cost settlement, civil money penalty [CMP] fine, provider bed tax, licensing fees). This does not include financial issues that are in the appeal process.
 - g. Failure to comply with a State correction notice order.
 - h. A determination by the Department that any nursing home owned or operated by the applicant or the applicant's owner is no longer able to provide adequate patient care.
 - i. The sanction of the applicant, applicant's owner or any corporate officer of the applicant or owner that results in "exclusion" from participation in the Medicare or Medicaid program.
2. The applicant will provide documentation of compliance with any outstanding requirements of Condition 1 of this approval within 1 year of the effective date of this Certificate of Need.
3. The Department in its discretion may approve or direct the Applicant or approve action proposed by the applicant to improve or remedy any deficiencies or requirements in Condition 1 as an alternative, or in addition to documentation of compliance required by condition 2.



**Public Comment of Alison Hirschel, Michigan Advocacy Project and Michigan Campaign for Quality Care, in support of the Proposed modifications to The Nursing Home and Hospital Long Term Care Unit Bed Standards
June 21, 2006**

The Michigan Advocacy Project and the Michigan Campaign for Quality Care wish to express support for the proposed changes to the Nursing Home and Long Term Care Unit Beds Standards which are being presented today. We want to thank Commissioner Brad Cory and Michigan Department of Community Health Deputy Director Jan Christensen for their significant and thoughtful efforts to revise the standards and their willingness to invite a wide range of stakeholders to provide in-put as the modifications were being drafted.

We support the modifications for the following reasons:

1. We have long believed that certificates of need should only be issued to applicants who have demonstrated their ability to provide quality care. These modifications are a significant step forward in that important direction and consistent with previous efforts by this Commission to promote quality in the Facility Innovative Design program.
2. The modifications are consistent with the goals and recommendations of the Governor's Medicaid Long Term Care Task Force which endorsed a variety of efforts to promote quality across the long term care spectrum.
3. The modified standards reward high quality and serve as an important incentive for providers to maintain quality over a period of time.
4. The standards also ensure that providers who have troubled homes or enforcement challenges focus on addressing those issues before taking responsibility for additional beds.
5. The modifications are consistent with other efforts to promote quality including standards developed by the Department to determine when facilities may obtain additional Medicaid certified beds and thus create a more consistent focus on quality across various Departmental programs and systems.

We thank you again for your consideration of these proposed modifications and urge the Commission to vote in support of these important changes.

If you have any questions please feel free to contact me at 517-333-0221.

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Website: <http://www.mplp.org>



28000 Dequindre
Warren, Michigan 48092

Norma Hagenow, Chair
Certificate of Need Commission
Health Facilities Section – Certificate of Need
320 S. Walnut Street
Lewis Cass Building
Lansing, MI 48913

RE: CON Review Standards for Bone Marrow Transplantation (BMT) Services

Dear Commissioner Hagenow:

As a workgroup has been initiated to review the CON standards for BMT, it is St. John Health's position that there should be a review of the standards with regards to access and need for BMT programs. We ask the CON commission to **establish a charge and either assigns a SAC or ask the BMT work group to develop a need methodology for bone marrow transplantation programs in the State of Michigan.** There are several reasons for this including the following:

- There is *no rationale for the current methodology* to determine the number of allowed BMT services in the state. (Section 3(5)(a))
- The American Society of Clinical Oncology (ASCO) at their 2006 annual meeting concluded that BMT has evolved from an experimental approach of uncertain promise to a widely practiced treatment with a defined place in the management of malignant disease, particularly hematological malignancies [2006 Educational Book, 42nd Annual meeting, June 2-6; pages 387-396; www.asco.org]. *BMT can be conducted in community institutions* because it is now safer. ASCO sites that the safety has improved because of better supportive care, new conditioning regimens, and better management of side effects of transplantation. There has been *steady rise annually in the number of bone marrow/stem cell transplantation* (SCT) performed worldwide for a variety of reasons including:
 - Availability of allogeneic donors to patients who do not have a HLA-identical sibling have increased – through the use of Matched Unrelated Donors (MUD). The National Marrow Donor Program (NMDP) has stated that more than 10,000 transplants have now been done utilizing unrelated donors. There are now more than 4 million donors listed in the NMDP registry.
 - Transplantation can now be done safely in older patients – due to significant advances in supportive care and the introduction of non-myeloablative and reduced-intensity conditioning regimens.
 - The ASCO paper states the unfortunate fact that “not all patients with an available HLA-matched donor and an uncontroversial indication for



St John Health

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allogeneic SCT actually receive the treatment.” So, clearly there is limited access to BMT/SCT. As a practicing Hematologist/Oncologist exclusively in hematological malignancies where such a procedure is considered a standard of care, I can attest that access is also limited in our state. Some of the reasons are obvious, like the geographic distance from a transplant center. However, there are other, no less important reasons, some of which are as follows:

- Disruption of Continuity of Care. It is far more efficient and cost-effective to perform BMT in the same location where the oncologist patient relationship has been established. When transferring a patient to a transplant center, not only is continuity of care disrupted, but also there are additional costs incurred because tests are typically repeated. The oncologist has to relay all patient information to the center and agree on path of treatment and timing for transplant. This involves careful and time-consuming coordination on the part of the physicians involved. Post transplant, oncologists again need to spend time with the transplant center to understand prescribed treatment regimen and results again requiring time consuming coordination and fragmentation of patient care. Such environment creates additional costs and imposes hardships on the patient and referring oncologists. As a result, community oncologists do not readily refer their patients for this procedure, which in essence limits access to the procedure.
- Limiting the number of transplant centers greatly limits the visibility of the procedure among community oncologists, which affects the timely referral of their patients thus limiting access. For this reason, treating physicians in the community often don't seek BMT/SCT at all or not early in the course of disease where the procedure is most effective. Another outcome of limiting transplant centers is lack of familiarity of the great majority of the community oncologists with the procedure and their ability to effectively explain it to their patients. For many patients in whom the procedure is indicated, it is never even considered by the treating oncologist in the community. A transplant team on site is much more likely to advocate for the procedure to colleagues within their institution than what current transplant centers experts have done or can do at community centers.

At the workgroup discussion, there was confusion in the use of the terms like CAPACITY at existing transplant centers and ACCESS to transplantation. While our colleagues at current transplant centers are eager to accommodate referrals from the community state-wide (i.e. they feel they have capacity), accessibility of transplantation depends on other factors that are not visible to the transplant centers. Making BMT/SCT available to every patient in the state of Michigan who needs it goes beyond capacity at or access to the existing transplant centers. The lack of on-site transplant service in the community and the need to refer patients outside is so burdensome for both patients and referring physicians in the current environment that the procedure is clearly not being offered to all patients who are candidates; hence we are not making this procedure available/accessible to our patients.

St John Health
Page 3 of 3

Instead of referring patients to transplant when it is most appropriate, community physicians resort to treating patients with alternative methods like multiple salvage chemotherapy regimens, radiation therapy, etc. Such practice adds to the cost of health care and provides sub optimum care to patients. It is more cost-effective to perform BMT/SCT for a patient with lymphoma at first relapse, for example than to give one, two or three salvage regimens plus radiation therapy. This speaks strongly against the argument of adding cost to healthcare by setting up more transplant centers. Moreover, BMT/SCT is curative modality in such a case whereas the other approach is strictly palliative.

St. John Health advocates that the CON commission allow for a review of the standards to determine a needs methodology to support BMT centers where there is critical mass to support a program while meeting strict national and state programmatic clinical quality indicators for BMT.

Sincerely,

Ayad Al-Katib, M.D., FACP
Medical Director, VanEslander Cancer Center, St. John Health
Professor of Medicine, Wayne State University, School of Medicine

cc: CON Commission members

T:\clinical service lines\clinical networks\oncology clinical network\bmt workgroup\pub lic statement for 6-21-06

Robert Meeker



Spectrum Health

*Butterworth Campus*100 MICHIGAN STREET NE GRAND RAPIDS MI 49503-2560
616 391 1774 FAX 391 2745 www.spectrum-health.org

June 21, 2006

Norma Hagenow, Chair
 Certificate of Need Commission
 c/o Michigan Department of Community Health
 Certificate of Need Policy Section
 Capitol View Building
 201 Townsend Street
 Lansing, Michigan 48913

Dear Ms. Hagenow,

As an active participant in the discussions by the Bone Marrow Transplant (BMT) work group, Spectrum Health supports all of the decisions made by that group at their meeting on May 25, 2006. Clarification of the qualifications for "mentor" BMT programs, specification that necessary support services can be in buildings physically attached to the applicant hospital, and name corrections of national accrediting organizations all represent improvements in the Standards. We also agree that the minimum volume requirements should not be changed until new standards have been developed by the Foundation for the Accreditation of Cellular Therapy (FACT).

However, the work group was unable to achieve consensus about the appropriate number and distribution of adult BMT programs in the state. While some work group members expressed concern that residents of southeastern and mid-Michigan have inadequate access to BMT services, others suggested that existing BMT programs have sufficient capacity to provide BMT services to residents of these regions.

Members of the work group did, however, express general agreement that citizens from West Michigan experience unacceptable access to adult BMT services. From Grand Rapids, the nearest full-service BMT program is in Ann Arbor, 125 miles away. While the cancer registry for Spectrum Health indicates that approximately fifty (50) adults would have qualified for BMT in 2004, only thirty-five (35) adult patients from West Michigan, including those from other cancer registries, received BMT services, according to the Michigan Inpatient Database. Our concern is that cancer patients who could benefit from this treatment modality are seeking alternative treatments, due to the unavailability of adult BMT services in West Michigan. As the Commission continues to make needed revisions to the CON Review Standards for Bone Marrow Transplantation Services, we urge that you address the access concerns of West Michigan for this important modality.

Along with addressing the access issue, changes should be considered to the Comparative Review Criteria. Factors such as distance to existing BMT programs, availability of necessary support services, and volume of relevant cancer cases could be used to distinguish among competing, qualified CON applications for bone marrow transplant services

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for BMT, and we urge that the CON Commission continue the process to revise these Standards in an expeditious manner. Spectrum Health is pleased to participate in this process, as appropriate.

Sincerely,

Robert A. Meeker
 Strategic Program Manager

Lakshmi Amarnath

6/20/06

Bone Marrow Transplants Performed in Michigan
Year 2000 through Year 2005

Year 2000

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	70	3	19	100	5	18	215
Oakwood	13	-	-	8	-	-	21
Henry Ford	22	-	-	16	-	-	38
Harper/Karmanos	54	2	-	123	2	8	189
Spectrum/Butterworth	-	1	4	-	-	9	14
Total	159	6	23	247	7	35	477

Year 2001

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	100	2	5	86	1	27	221
Oakwood	7	-	-	7	-	-	14
Henry Ford	15	-	-	20	-	-	35
Harper/Karmanos							211*
Spectrum/Butterworth	-	-	4	-	-	13	17
Total							498

Year 2002

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	93	3	9	110	3	14	232
Oakwood	7	-	-	4	-	-	11
Henry Ford	19	-	-	17	-	-	36
Harper/Karmanos	64	2	4	44	1	8	123
Spectrum/Butterworth	-	-	3	-	-	10	13
Total	183	5	16	175	4	32	415

*82 Autologous and 129 Allogeneic procedures performed in 2001 for a total of 211-
source www.marrow.org

Source: Annual Hospital Statistical Survey (2000 to 2005)
BMTData06

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6/20/06

Year 2003

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	103	2	20	104	2	26	257
Oakwood	7	-	-	8	-	-	15
Henry Ford	28	1	-	22	1	-	52
Harper/Karmanos	46	-	9	42	1	14	112
Spectrum/Butterworth	-	-	6	-	-	6	12
Total	184	3	35	176	4	46	448

Year 2004

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	104	1	9	84	4	16	218
Oakwood	7	-	-	4	-	-	11
Henry Ford	31	-	-	18	-	-	49
Harper/Karmanos	47	1	1	48	10	18	125
Spectrum/Butterworth	-	-	5	-	2	7	14
Total	189	2	15	154	16	41	417

Year 2005

Hospital	Autologous			Allogeneic			Total
	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	Adult Age>21	Age Group 18-20	Pediatric 0 - 17	
Univ. of Michigan	103	3	9	75	2	16	208
Oakwood	7	0	0	9	1	0	17
Henry Ford	26	0	0	17	0	0	43
Harper/Karmanos	49	1	7	85	1	12	155
Spectrum/Butterworth	0	1	6	-	2	6	15
Total	185	5	22	186	6	34	438

Source: Annual Hospital Statistical Survey (2000 to 2005)
BMTData06

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Date 15 June 2006

To: Commissioners of the Certificate of Need Commission

Re: Bone Marrow Transplantation Services

From: Samuel M. Silver, MD, PhD
University of Michigan

I would like to thank the Commissioners of the Certificate of Need Commission for the opportunity to participate in the Informal BMT Workgroup that was held in Lansing on 25 May. I will, unfortunately, be unable to participate in Commission's meeting on 21 June.

I would like to summarize the points of discussion that I made during the Workgroup meeting on the issue of number of BMT services in Michigan:

1. From a Michigan-wide BMT program access point of view, there are adequate in-State services to provide prompt hematopoietic stem cell consultations and treatment from the existing programs. This will be true, even when the Oakwood Program ceases to operate. Initiating additional BMT programs would add capacity to an already under utilized service.
2. Issues of travel distance to the nearest Adult BMT program for patients living in western Michigan are certainly appropriate for discussion; however, it is not clear what the remedy would be.
3. The number of transplants performed in the State of Michigan has not increased over the last few years. I discussed the reasons why I believe that the number of hematopoietic stem cell transplants might actually decrease over the next few years:
 - a. New, less toxic, non-transplant therapy, ie targeted therapies (Gleevec in CML), new agents (thalidomide and Velcade in myeloma) may replace transplants.
 - b. Sub-ablative allogeneic transplants that require graft-versus-tumor effect for disease control still can cause significant morbidity and mortality for the very population that they are targeted for: the older, sicker transplant patient.
 - c. Non-hematopoietic stem cell transplants (ie, to replace damaged myocardium) are certainly an interesting technology, and are to be considered experimental. If these transplants are proven to be effective, this issue can be addressed at a future CON meeting.
4. Existing BMT programs in Michigan need to operate at a utilization rate necessary to maintain the highest possible quality standards. Incremental

program(s) in the state would dilute an existing programs' patient population, thus negatively impacting the quality of care to its patients.

5. Additional BMT program(s) in the State of Michigan will increase the cost to society

Thank you for allowing me to participate in this discussion. If you have any questions, please feel free to contact me.

Samuel M. Silver, MD, PhD
Professor, Internal Medicine, Division Hematology/Oncology
University of Michigan Medical School

Director, University of Michigan Cancer Center Network

Medical Director, Medical Management Center
University of Michigan Health System

Psychiatric Beds and Services Workgroup 2006
Report to the Certificate of Need Commission

June 21, 2006

The Psychiatric Beds and Services Workgroup was established at the March 21, 2006 Certificate of Need (CON) Commission Meeting. The Commission assigned the Workgroup to follow up on the public comments received regarding these Standards at the Public Hearing on January 31, 2006. The following is an overview of the public comments received:

- Received three (3) recommendations to review the Bed Need Methodology for possible modifications.
- Received four (4) recommendations to review the Planning Areas for possible modifications.
- Received three (3) recommendations for the addition of individual facility high occupancy language.
- Received four (4) recommendations for review of the Replacement Zone for possible modifications.
- Received one (1) recommendation for the addition of Relocation definition and language.
- Received one (1) recommendation for removal of Section 6(2)(f).
- Received one (1) recommendation for review of the Michigan Mental Health Commission Final Report for potential inclusion.

In addition, the CON Program Section requested several technical changes and review of the occupancy rates for possible adjustment. The public comments received and the CON Program Section requests make up the list of discussion items for the Workgroup.

Meetings were held in May and June with the next meeting scheduled for July. The Workgroup has brainstormed on possible solutions, discussing the advantages and disadvantages of each suggestion, and is working towards a group consensus. One interesting package of three solutions is being researched. Draft language and feasibility of implementation will be reviewed in more detail at the July meeting.

The Workgroup has evaluated the meeting model. While participants have given overall positive feedback on the meetings and documents supplied, three (3) suggestions or avenues for improvement were noted as follows:

- Solicit participation from small or low occupancy facilities.
- Solicit participation from non-provider groups.
- Apply real situations to any draft language to ensure that language meets the Workgroup's intent and there are not unforeseen repercussions.

Overall, from the Chair's perspective, the Workgroup members have done an excellent job of focusing on what would be best from a public policy perspective for Michigan citizens while still balancing their advocacy for their individual organizations. Staff support has truly enhanced the process with timely, well-drafted working documents that have facilitated discussion. We have made significant progress in two meetings.

Respectfully submitted,

Dorothy E. Deremo, CON Commission Liaison
Psychiatric

Beds

and

Services

Workgroup

DRAFT

Cardiac Catheterization Services

STANDARD ADVISORY COMMITTEE (SAC) CHARGE

The Cardiac Catheterization Services SAC is charged to review and recommend necessary changes to the Cardiac Catheterization Services Standards as outlined below:

1. Review whether facilities providing cardiac catheterization services in Michigan should be required to participate in either or both Blue Cross of Michigan Cardiovascular Consortium (BMC2) registry and the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR).
2. Review and examine minimum physician volume requirements and institutional volume requirements in the Certificate of Need Review Standards for Cardiac Catheterization Services.

Cheryl Miller



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www.trinity-health.org

June 21, 2006

Norma Hagenow, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building
201 Townsend Street
Lansing, Michigan 48913

RE: Issues for Inclusion in Charges to Cardiac Catheterization and Open Heart Surgery SACs

Dear Ms. Hagenow,

As the CON Commission considers the formal charges for the upcoming Cardiac Catheterization and Open Heart Surgery Standard Advisory Committees (SACs), I would like to provide testimony on behalf of Trinity Health. As the fourth largest Catholic health system in the country, Trinity Health operates 12 hospitals in Michigan that include urban and rural, teaching and non-teaching facilities. Four of our Michigan hospitals currently offer open heart surgery services and two others offer emergency PCI services.

Concerning the evaluation and revision of the Cardiac Catheterization Standards, we would like to stress the importance that the following issues be incorporated into the final charge to the SAC:

- Minimum annual volumes for hospitals and physicians pertaining to:
 - Maintenance of an approved program
 - Replacement/upgrade of equipment
 - Expansion of services
- Update definitions, including clinical codes
- Review/revise procedure groupings, weights and procedure equivalents
- Clarify whether ICDs and other Electrophysiology Services are to be categorized as diagnostic, therapeutic or both
- Clarify the distinction, if any, between Multi-Purpose Special Procedure Rooms (MPSPRs) and Catheterization Labs versus other non-cardiac peripheral vascular angiography
- Should there be the policy for transferring a cardiac cath CON from hospital A to hospital B?
 - Only within a system or only within a geographic limitation or not at all
- Elective PCI at facilities without onsite open heart surgery backup
 - There is growing interest for selected Michigan hospitals to participate in the C-Port Elective research program. We encourage dialogue to consider a time-limited CON to allow carefully selected hospitals to participate in this important research initiative.

We serve together in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit, to improve the health of our communities and to steward the resources entrusted to us.

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- Concerning new and emerging technology:
 - How will 64-slice CT scanners impact the volume of cath labs and should the volume requirements be adjusted accordingly?
 - Clinical research now suggests that some strokes and migraines may be caused by a cardiac defect called PFO (patent foramen ovale), or a hole in the wall that divides the right and left upper chambers of the heart. Some of these can be repaired by catheter-based techniques. The cath standards need to acknowledge these procedures and determine an appropriate procedure equivalent weight.

Concerning issues in need of evaluation and revision in the Open Heart Surgery Standards, Trinity Health would like to suggest that the following issues be incorporated into the final charge to the SAC:

- Definition of OHS – which codes should be included?
 - Should CABG procedures be counted separately from other OHS procedures?
- Minimum annual volumes:
 - Adult compliance/maintenance
 - Pediatric compliance/maintenance
 - Program Initiation
- Should the demand methodology be adjusted to reflect declining OHS volumes due to increased use of stents, statins and other non-surgical interventions?
- Adult congenital cases – do these types of cases need special consideration or not?
 - What is the appropriate definition of pediatric?
- Serious consideration must be given to mandating the participation in a quality/risk adjusted outcomes/database participation
 - Blue Cross of Michigan Cardiovascular Consortium
 - STS National Database (Society of Thoracic Surgeons)
 - Tie a quality monitoring system to project delivery requirements and compliance
- Planning areas still appropriate?
- Commitment of data to initiate a new program
 - Geographic restrictions?
 - Within a system?
 - Duration of commitment?
- As annual procedure thresholds change over time, should a hospital's compliance status be based on the more current volume requirements or the volume in effect at the time of CON approval?
- Should there be the policy for transferring a OHS CON from hospital A to hospital B?
 - Only within a system or only within a geographic limitation or not at all

On behalf of Trinity Health, thank you for the opportunity to provide input into the important charges of the Cardiac Cath and Open Heart Surgery Standard Advisory Committees.

Sincerely,



Narendra Kini, MD
Executive Vice President
Clinical Operations Improvement

We serve together in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit, to improve the health of our communities and to steward the resources entrusted to us.

Respect • Social Justice • Compassion • Care of the Poor and Underserved • Excellence

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DRAFT

Open Heart Surgery Services

STANDARD ADVISORY COMMITTEE (SAC) CHARGE

The Open Heart Surgery Services SAC is charged to review and recommend necessary changes to the Open Heart Surgery Services Standards regarding the following two issues:

1. Review and consider public reporting of risk adjusted volumes.
2. Review and determine minimum institutional volume requirements in the Certificate of Need Review Standards for Open Heart Surgery Services.

CERTIFICATE OF NEED
Quarterly Program Section Activity Report to the CON Commission
 January 1, 2006 through March 31, 2006 (FY 2006)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the Program Section in accordance with Section 22215(1)(e) of the Public Health Code.

Measures

Administrative Rule 325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	174	316
Letters of Intent Processed within 15 days	168	305

Administrative Rule 325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	80	193
Applications Processed within 15 Days	80	193
Applications Incomplete/More Information Needed	76	187

Administrative rules 325.9206 and 325.9207 requires the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	35	0	79	0
Substantive Applications	49	0	85	1
Comparative Review Applications	2	0	4	0

Administrative Rule 325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	Most Recent Quarter	Year-to-Date
Emergency Applications Received	3	3
Decisions Issued within 10 workings Days	3	3

Quarterly Program Section Activity Report
 January 1, 2006 through March 31, 2006 (FY 2006)
 Page 2 of 2

Measures – continued

Administrative Rule 325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	22	1	56	10

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	106	203
FOIA Requests Processed on Time	106	203
Number of Applications Viewed Onsite	56	134

FOIA – Freedom of Information Act.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

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

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2005												2006											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J	F	M*	A	M	J*	J	A	S*	O*	N	D*
Bone Marrow Transplantation Services**			—		P	▲F							PH		D	•	•	•D	•	•	—	P		▲F
Cardiac Catheterization Services																		D	S	■	■	■	■	
Computed Tomography (CT) Scanner Services – I-Cat**											•		•	•	D	•	•	•D	P		▲F			
Hospital Beds**	P		▲F		P	▲			FD					■	■	■	■	■	■	■	—		P	▲F
Hospital Beds – LTACs**														•	D•	•	•	D						
Magnetic Resonance Imaging (MRI) Services**			—		P	▲F							PH		D	•	•	•D	•	•	—	P		▲F
Nursing Home and Hospital Long-term Care Unit Beds**											•				•D	•	•	•D	P		▲F			
Open Heart Surgery Services																		D	S		■	■	■	■
Positron Emission Tomography (PET) Scanner Services**			D						D	S				■	■	■	■	■	■	■	—		P	▲F
Psychiatric Beds and Services**	P		▲F		P	▲F							PH		D	•	•	•D	•	•	•D			
New Medical Technology Standing Committee			M			M			M		M				MR			M	S		•M			M
Commission & Department Responsibilities			D			D			D		D				DR			M			M			M

- KEY**
- - Receipt of proposed standards/documents, proposed Commission action
 - * - Commission meeting
 - - Staff work/Standard advisory committee meetings
 - ▲ - Consider Public/Legislative comment
 - ** - Current in-process standard advisory committee or Informal Workgroup
 - - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
 - A - Commission Action
 - C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
 - D - Discussion
 - F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
 - M - Monitor service or new technology for changes
 - P - Commission public hearing/Legislative comment period
 - PH - Public Hearing for initial comments on review standards
 - R - Receipt of report
 - S - Solicit nominations for standard advisory committee or standing committee membership

Approved June 21, 2006

Updated

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.

CON Commission Meeting
Wednesday, June 21, 2006

Approved September 19, 2006
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SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2007
Bone Marrow Transplantation Services	September 21, 2005	2006
Cardiac Catheterization Services	June 4, 2004	2005
Computed Tomography (CT) Scanner Services	June 4, 2004	2007
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	May 27, 2005	2005
Magnetic Resonance Imaging (MRI) Services	October 17, 2005	2006
Megavoltage Radiation Therapy Services/Units	January 30, 2006	2008
Neonatal Intensive Care Services/Beds (NICU)	June 4, 2004	2007
Nursing Home and Hospital Long-Term Care Unit Beds, Addendum for Special Population Groups, and Addendum for New Design Model Pilot Program	December 3, 2004	2007
Open Heart Surgery Services	June 4, 2004	2005
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	June 4, 2004	2005
Psychiatric Beds and Services	October 17, 2005	2006
Surgical Services	June 5, 2006	2008
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 4, 2004	2007

*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 January of each 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.