

1 MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
2
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS**
4 **FOR HEART/LUNG AND LIVER TRANSPLANTATION SERVICES**
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
9

10 **Section 1. Applicability**

11
12 ~~Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects~~
13 ~~approved and Certificates of Need issued under Part 222 of the Code which involve heart/lung or liver~~
14 ~~transplantation services. THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND~~
15 ~~DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE~~
16 ~~CODE, HEART/LUNG AND LIVER TRANSPLANTATION IS A ARE COVERED CLINICAL SERVICES.~~
17 ~~THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE~~
18 ~~CODE, BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION~~
19 ~~22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.~~

20
21 ~~(2) Heart/lung or liver transplantation is a covered clinical service for purposes of Part 222 of the~~
22 ~~Code.~~

23
24 ~~(3) For purposes of Part 222 a separate CON is required for heart/lung or liver transplantation~~
25 ~~services. A CON issued for a heart/lung transplantation service includes a service that performs heart,~~
26 ~~heart/lung, or lung transplant procedures and a separate CON is not required to begin performing any of~~
27 ~~these procedures if one or more are not performed initially.~~

28
29 ~~(4) The Department shall use sections 3, 4, 5, and 11, as applicable, in applying Section 22225(1) of~~
30 ~~the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

31
32 ~~(5) The Department shall use sections 7, 8, 9, and 10, as applicable, in applying Section 22225(2)(c)~~
33 ~~of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

34
35 **Section 2. Definitions**

36
37 Sec. 2. (1) As used in these standards:

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

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

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

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

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

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

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

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

59 | ~~(hG) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility~~
60 | ~~HOSPITAL authorized by license and listed on that licensee's certificate of licensure, or (ii) in the case of~~
61 | ~~a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility~~
62 | ~~as authorized by license and listed on that licensee's certificate of licensure.~~

63 | ~~(iH) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6~~
64 | ~~and 1396r-8 to 1396v.~~

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

70 | ~~(kJ) "OPTN" or "Organ Procurement and Transplantation Network" OR "OPTN" means the~~
71 | ~~organization contracted by the federal Department of Health and Human Services to operate the organ~~
72 | ~~procurement and transplantation network. "ORGAN PROCUREMENT ORGANIZATION" OR "OPO"~~
73 | ~~MEANS AN ORGAN PROCUREMENT ORGANIZATION AS DEFINED BY CFR TITLE 42, PART~~
74 | ~~485.302.~~

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

77 | ~~(mL) "Planning area" means the state of Michigan.~~

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

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

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

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

109 | recipient(s) into the program;

110
111 | (2) The definitions of Part 222 shall apply to these standards.

112
113 | **Section 3. Requirements for approval--all applicants**

114
115 | Sec. 3. (1) An applicant proposing to perform either a heart, heart/lung, or lung or liver transplantation
116 | service shall demonstrate that it offers all of the following services or programs:

117 | (a) operating rooms;

118 | (b) anesthesiology;

119 | (c) microbiology and virology laboratory;

120 | (d) continuous availability, either on-site or on-call, of:

121 | (i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear
122 | medicine; and

123 | (ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical
124 | and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support;
125 | cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.

126 | (e) dialysis;

127 | (f) infectious disease;

128 | (g) inpatient-outpatient social work;

129 | (h) inpatient-outpatient psychiatry/psychology;

130 | (i) clinical research;

131 | (j) a histocompatibility laboratory that meets the standards of the American Society for
132 | Histocompatibility and Immunogenetics or an equivalent organization THAT IS AN APPROVED

133 | MEMBER OF THE OPTN, either on-site or through written agreement;

134 | (k) other support services, as necessary, such as physical therapy and rehabilitation medicine;

135 | (l) continuous availability of anatomic and clinical pathology and laboratory services including
136 | clinical chemistry, immuno-suppressive drug monitoring and tissue typing;

137 | (m) continuous availability of red cells, platelets, and other blood components;

138 | (n) an established organ donation protocol, with brain death protocol, consistent with applicable
139 | Michigan law; and

140 | (o) a written TRANSPLANT agreement with Michigan's federally designated organ procurement
141 | organization (OPO) to promote organ donation at the applicant hospital(s).

142
143 | (2) An applicant must provide, ~~at the time the CON application is submitted,~~ an implementation plan
144 | for the proposed transplantation service. IMPLEMENTATION PLAN MEANS A PLAN THAT
145 | DOCUMENTS HOW A PROPOSED TRANSPLANTATION SERVICE WILL BE INITIATED WITHIN THE
146 | TIME PERIOD SPECIFIED IN THESE STANDARDS OR THE CON RULES. AT A MINIMUM, THE
147 | IMPLEMENTATION PLAN SHALL IDENTIFY:

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

153 | (IB) THE TIMETABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN
154 | SUBSECTION (I); AND

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

160
161
162 | (3) An application which proposes a joint sharing arrangement for a transplantation service which

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

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

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

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

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

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

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

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

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

182
183 (4) An applicant shall provide verification of Medicaid participation. AN APPLICANT THAT IS A
184 NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF
185 MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS
186 FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. at the time the application is
187 submitted to the Department. If the required documentation is not submitted with the application on the
188 designated application date, the application will be deemed filed on the first applicable designated
189 application date after all required documentation is received by the Department.

190
191 (5) AN APPLICATION WHICH PROPOSES A JOINT SHARING ARRANGEMENT FOR A HEART,
192 OR HEART/LUNG, OR LUNG OR LIVER TRANSPLANTATION SERVICE WHICH INVOLVES MORE
193 THAN ONE LICENSED SITE, WHERE THE LICENSED SITES IN THE JOINT SHARING
194 ARRANGEMENT ARE NOT PART OF A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN
195 MICHIGAN, SHALL NOT BE REQUIRED TO MEET SECTION 4(1) OR 5(1) OF THESE STANDARDS,
196 IF AN APPLICANT CAN DEMONSTRATE ALL OF THE FOLLOWING:

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

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

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

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

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

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

217 HEART OR HEART/LUNG OR LUNG OR LIVER TRANSPLANTATION SERVICES;
218 (VII) THE APPLICANT SHALL AGREE THAT THE TWO LICENSED SITES WILL JOINTLY APPLY
219 TO PERFORM TRANSPLANTATION PROCEDURES UNDER THE SAME OPTN CERTIFICATION;
220 AND
221 (VIII) THE APPLICANT PROJECTS A MINIMUM OF 12 ADULT AND 10 PEDIATRIC HEART, OR
222 HEART/LUNG, OR LUNG OR LIVER TRANSPLANTATION PROCEDURES IN THE SECOND 12-
223 MONTHS OF OPERATION FOLLOWING THE DATE ON WHICH THE FIRST HEART, OR
224 HEART/LUNG, OR LUNG OR LIVER TRANSPLANT PROCEDURE IS PERFORMED, AND ANNUALLY
225 THEREAFTER.
226
227

228 **Section 4. Additional requirements for applicants seeking approval to provide heart, or heart/lung**
229 **or lung transplantation services**
230

231 Sec. 4. (1) Approval of an application proposing to provide heart, or heart/lung or lung transplantation
232 services shall not result in more than three (3) heart, or heart/lung or lung transplantation services in the
233 planning area. In evaluating compliance with this subsection, an application submitted or a certificate
234 approved pursuant to Section 43(5) of these standards shall be considered as a single service.
235

236 (2) Except for an application pursuant to Section 43(5) of these standards, an applicant for a heart,
237 or heart/lung or lung transplantation service shall project a minimum of 12 heart, or heart/lung or lung
238 transplantation procedures annually in the second 12-months of operation following the date on which the
239 first heart, or heart/lung or lung transplant procedure is performed and annually thereafter.
240

241 (3) An applicant proposing to provide heart, or heart/lung or lung transplantation services shall
242 demonstrate that it either operates an existing renal transplant service or has a written agreement with a
243 renal transplant service in the same hospital subarea that ensures that the professional expertise of the
244 renal transplant service is readily available to the proposed transplantation service.
245

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

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

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

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

255 (d) continuously available coagulation laboratory services; and

256 (e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on
257 demand.
258

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

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

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

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

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

271 | ~~procedures will be performed and a single licensed site where all of the pediatric transplantation~~
272 | ~~procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;~~
273 | ~~— (v) the licensed site at which the pediatric transplantation service will be provided shall have~~
274 | ~~admitted or discharged at least 7,000 pediatric patients during the most recent 12-month period for which~~
275 | ~~verifiable data are available to the Department;~~
276 | ~~— (vi) the licensed site that is designated as the site at which adult procedures will be performed is~~
277 | ~~authorized under former Part 221 or Part 222, at the time the application is submitted to the Department,~~
278 | ~~to perform adult heart or heart/lung or lung transplantation services;~~
279 | ~~— (vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation~~
280 | ~~procedures under the same OPTN certification; and~~
281 | ~~— (viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung~~
282 | ~~transplantation procedures in the second 12-months of operation following the date on which the first~~
283 | ~~heart or heart/lung or lung transplant procedure is performed, and annually thereafter.~~

284 |
285 | **Section 5. Additional requirements for applicants seeking approval to provide liver**
286 | **transplantation services**

287 |
288 | Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not
289 | result in more than three (3) liver transplantation services in the planning area. **IN EVALUATING**
290 | **COMPLIANCE WITH THIS SUBSECTION, AN APPLICATION SUBMITTED OR A CERTIFICATE**
291 | **APPROVED PURSUANT TO SECTION 3(5) OF THESE STANDARDS SHALL BE CONSIDERED AS A**
292 | **SINGLE SERVICE.**

293 |
294 | (2) **EXCEPT FOR AN APPLICATION PURSUANT TO SECTION 3(5) OF THESE STANDARDS,** an
295 | applicant for a liver transplantation service shall project a minimum of 12 liver transplantation procedures
296 | annually in the second 12-months of operation following the date on which the first liver transplant
297 | procedure is performed, and annually thereafter.

298 |
299 | (3) An applicant proposing to provide liver transplantation services shall demonstrate that it either
300 | operates an existing renal transplant service or has a written agreement with a renal transplant service in
301 | the same hospital subarea that ensures that the professional expertise of the renal transplant service is
302 | readily available to the proposed transplantation service.

303 |
304 | (4) An applicant proposing to provide a liver transplantation service shall demonstrate that it offers all
305 | of the following services or programs:

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

314 |
315 |
316 | **Section 6. REVIEW STANDARDS FOR Additional requirements for applications included in**
317 | **comparative reviews**

318 |
319 | Sec. 6. (1) Any application subject to comparative review under Section 22229 of the Code, being
320 | Section 333.22229 of the Michigan Compiled Laws, or **UNDER** these standards shall be grouped and
321 | reviewed **COMPARATIVELY** with other applications in accordance with the CON rules, **applicable to**
322 | **comparative reviews.**

323 |
324 | (2)(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform

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

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

338	Number of	
339	Transplant Programs	Points
340	in HSA	Awarded
341		
342	Two or more programs	0
343	One program	2
344	No programs	4

345
346 (c) A qualifying project will have up to 4 points awarded based on the percentage of the
347 medical/surgical indigent volume at the licensed ~~hospital~~ site at which the proposed heart/lung or liver
348 transplantation service will be provided in accordance with the following:

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

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

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

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

373
374 (3) Each application in a comparative review group shall be individually reviewed to determine
375 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
376 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the
377 Code and these standards. If the Department determines that one or more of the competing applications
378 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The

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

389
390 (4) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A
391 LOWER POINT REWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH
392 COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE
393 DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE
394 AWARDED FROM CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION
395 WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION
396 WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE
397 CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL
398 AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT
399 IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO
400 RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED. ~~No points will be~~
401 ~~awarded to an applicant under specific subsections of Section 6 if information presented in Section 6 is~~
402 ~~inconsistent with related information provided in other portions of the CON application.~~

403 404 **Section 7. Project delivery requirements -- terms of approval ~~for all applicants~~**

405
406 Sec. 7. (1) An applicant shall agree that, if approved, the services shall be delivered in compliance
407 with the following terms of CON approval:

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

411 (b) Compliance with applicable safety and operating standards.

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

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

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

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

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

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

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

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

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

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

433 related to the proposed transplantation service.

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

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

442 (x) The applicant shall participate in a data collection network established and administered by the
443 Department or its designee. The data may include, but is not limited to, annual budget and cost
444 information, operating schedules, through-put schedules, demographic and diagnostic information,
445 patient survival rates at both 12 and 24 months following the transplant procedure, primary and
446 secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length
447 of stay, the volume of care provided to patients from all payor sources, and other data requested by the
448 Department and approved by the CON Commission. The applicant shall provide the required data on an
449 individual basis for each designated licensed site; in a format established by the Department; and in a
450 mutually agreed upon media. The Department may elect to verify the data through on-site review of
451 appropriate records.

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

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

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

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

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

460 (xii) The applicant shall provide the Department with a notice stating the date on which the first
461 transplant procedure is performed and such notice shall be submitted to the Department consistent with
462 applicable statute and promulgated rules.

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

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

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

470
471 (2) The agreements and assurances required by this section, ~~and sections 8, 9, and 10,~~ as
472 applicable, shall be in the form of a certification ~~authorized by the governing body of~~ **AGREED TO BY** the
473 applicant or its authorized agent.

474
475 **Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver**
476 **transplantation services**

- 477
478 ~~— Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:~~
479 ~~— (a) a written agreement with the federally approved organ procurement organization whose~~
480 ~~designated service area includes the location of the proposed transplantation service;~~
481 ~~— (b) organ preservation capability;~~
482 ~~— (c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;~~
483 ~~— (d) an organized 24-hour communication service capable of serving the transplant team and others,~~
484 ~~as appropriate;~~
485 ~~— (e) a cyclosporine assay laboratory with results available on the same day;~~
486 ~~— (f) an immunologic monitoring laboratory;~~

- 487 —(g) a specialized inpatient transplantation unit;
- 488 —(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in
- 489 conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient
- 490 and managing immuno-suppressed patients.
- 491 —(i) a medical staff and governing board policy that provides for the selection of candidates for organ
- 492 transplantation procedures in accordance with the patient selection criteria approved by the Department;
- 493 —(j) an ethics committee or human use committee to review and approve the institution's protocols
- 494 related to organ transplantation, including protocols involving the selection of donors and recipients; and
- 495 —(k) a multi-disciplinary transplant recipient evaluation committee.
- 496
- 497 —(2) An applicant shall agree that the transplantation service shall be staffed with qualified adult and
- 498 pediatric, as applicable, transplant surgeon(s) and transplant physician(s). For purposes of evaluating
- 499 this subsection, the Department shall consider it *prima facie* evidence as to the training of the surgeon(s)
- 500 and physician(s) if they meet the requirements for certification by Medicare or the OPTN. However, the
- 501 applicant may submit and the Department may accept other evidence that the surgeon(s) and
- 502 physician(s) are qualified.
- 503

504 **Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung**

505 **transplantation services**

506

- 507 — Sec. 9. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be
- 508 staffed and provided by at least the following:
- 509 —(a) cardiologists or surgeons trained in endocardial biopsy;
- 510 —(b) cardiologists and surgeons trained in immunosuppression techniques;
- 511 —(c) both adult and pediatric, as appropriate, cardiologists and surgeons;
- 512 —(d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants
- 513 in animals in a setting simulating the human situation;
- 514 —(e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with
- 515 one surgical team continuously available for organ retrieval thereby enabling a second team to
- 516 simultaneously begin performing a recipient operation;
- 517 —(f) a pathologist capable of diagnosing rejection on endocardial biopsies; and
- 518 (g) an anesthesiologist trained in open heart surgery.
- 519 —(2) An applicant must demonstrate heart transplant patient survival rates at one year and two years
- 520 after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must
- 521 demonstrate patient survival rates at one and two years after transplantation of no less than the national
- 522 average survival rate for the specific transplant type for the most recent year for which data is published
- 523 by the OPTN.
- 524

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

526

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

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

544 |
545 | ~~—(2) The applicant shall establish and maintain all of the following:~~
546 | ~~—(a) nuclear HID biliary scan availability;~~
547 | ~~—(b) a continuously available coagulation laboratory; and~~
548 | ~~—(c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of~~
549 | ~~plasma on demand.~~

550 |
551 | ~~—(3) An applicant must demonstrate patient survival rates at one year and two years after~~
552 | ~~transplantation of no less than the national average survival rate for the most recent year for which data is~~
553 | ~~published by the OPTN.~~

554 |
555 | **Section 118. Documentation of projections**

556 |
557 | **Sec. 118.** An applicant required to project volumes of service under sections 4 or 5 shall specify how
558 | the volume projections were developed. This specification of projections shall include a description of the
559 | data source(s) used, assessments of the accuracy of these data and the statistical method used to make
560 | the projections. Based on this documentation, the Department shall determine if the projections are
561 | reasonable.

562 | **Section 429. Health Service Areas**

563

564 | **Sec. 429. Counties assigned to each of the health service areas are as follows:**

565

566 | HSA

COUNTIES

567

568 | 1 | Livingston | Monroe | St. Clair
569 | | Macomb | Oakland | Washtenaw
570 | | Wayne |

571

572 | 2 | Clinton | Hillsdale | Jackson
573 | | Eaton | Ingham | Lenawee

574

575 | 3 | Barry | Calhoun | St. Joseph
576 | | Berrien | Cass | Van Buren
577 | | Branch | Kalamazoo

578

579 | 4 | Allegan | Mason | Newaygo
580 | | Ionia | Mecosta | Oceana
581 | | Kent | Montcalm | Osceola
582 | | Lake | Muskegon | Ottawa

583

584 | 5 | Genesee | Lapeer | Shiawassee

585

586 | 6 | Arenac | Huron | Roscommon
587 | | Bay | Iosco | Saginaw
588 | | Clare | Isabella | Sanilac
589 | | Gladwin | Midland | Tuscola
590 | | Gratiot | Ogemaw

591

592 | 7 | Alcona | Crawford | Missaukee
593 | | Alpena | Emmet | Montmorency
594 | | Antrim | Gd Traverse | Oscoda
595 | | Benzie | Kalkaska | Otsego
596 | | Charlevoix | Leelanau | Presque Isle
597 | | Cheboygan | Manistee | Wexford

598

599 | 8 | Alger | Gogebic | Mackinac
600 | | Baraga | Houghton | Marquette
601 | | Chippewa | Iron | Menominee
602 | | Delta | Keweenaw | Ontonagon
603 | | Dickinson | Luce | Schoolcraft

604

605 | **Section 4310. Effect on prior CON Review Standards; comparative reviews**

606

607 | **Sec. 4310. (1) These CON review standards supersede and replace the CON Review Standards for**
608 | **Extrarenal Transplantation FOR HEART/LUNG AND LIVER TRANSPLANTATION Services approved by**
609 | **the CON Commission on June 4, 1997MARCH 9, 2004 and effective on July 26, 1997JUNE 4, 2004.**

610

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