

1 | MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
2 |
3 | **CERTIFICATE OF NEED (CON) REVIEW STANDARDS**
4 | **FOR HEART/LUNG AND LIVER (HLL) 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 HLL services under Part
13 | 222 of the Code. A CON issued for a heart/lung transplantation service includes a service that performs
14 | heart, heart/lung, or lung transplant procedures, and a separate CON is not required to begin performing
15 | any of these procedures if one or more are not performed initially. Pursuant to Part 222 of the Code,
16 | heart/lung and liver transplantation are covered clinical services. The Department shall use these
17 | standards in applying Section 22225(1) of the code, being section 333.22225(1) of the Michigan Compiled
18 | Laws and Section 22225(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
19 |

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

25 | **Section 2. Definitions**
26 |

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

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

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

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

34 | ~~(dC)~~ "Department" means the Michigan Department of Community Health (MDCH).

35 | ~~(eD)~~ "Health service area" or "HSA" means the geographic area set forth in Section 9APPENDIX A.

36 | ~~(f) "Initiate" or "implement" means the performance of the first transplant procedure. The term of an~~
37 | ~~approved CON shall be 18 months or the extended period established by Rule 325.9403(2).~~

38 | ~~(gE)~~ "Licensed site" means the location of the hospital authorized by license and listed on that
39 | licensee's certificate of licensure.

40 | ~~(hF)~~ "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396-r-6 and TO
41 | 1396-r-8 to G AND 1396I TO 1396v1396U.

42 | ~~(iG)~~ "Organ Procurement and Transplantation Network" or "OPTN" means the organization contracted
43 | by the Federal Department of Health and Human Services to operate the Organ Procurement and
44 | Transplantation Network.

45 | ~~(jH)~~ "Organ Procurement Organization" or "OPO" means an organ procurement organization as
46 | defined by CFR Title 42, Part 485.302.

47 | ~~(kI)~~ "Pediatric" means any patient less than 15 years of age or any patient with congenital anomalies
48 | related to the proposed transplantation service.

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

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

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

71 |
72 | (2) The definitions of Part 222 shall apply to these standards.
73 |

74 | **Section 3. Requirements ~~for all applicants~~ TO INITIATE A HEART, HEART/LUNG OR LIVER**
75 | **TRANSPLANTATION SERVICE**

76 |
77 | Sec. 3. ~~(1) Initiate or implement means the performance of the first transplant procedure. The term of~~
78 | ~~an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).~~

79 |
80 | ~~(1)~~ An applicant proposing to INITIATE ~~perform~~ either a heart, heart/lung, lung or liver transplantation
81 | service shall demonstrate that it offers all of the following services or ~~programs~~ SPECIALTIES:

- 82 | (a) operating rooms;
- 83 | (b) anesthesiology;
- 84 | (c) microbiology and virology laboratory;
- 85 | (d) continuous availability, either on-site or on-call, of:
 - 86 | (i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear
87 | medicine; and
 - 88 | (ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical
89 | and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support;
90 | cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.
- 91 | (e) dialysis;
- 92 | (f) infectious disease;
- 93 | (g) inpatient-outpatient social work;
- 94 | (h) inpatient-outpatient psychiatry/psychology;
- 95 | (i) clinical research;
- 96 | (j) a histocompatibility laboratory that meets the standards of the American Society for
97 | Histocompatibility and Immunogenetics or an equivalent organization that is an approved member of the
98 | OPTN, either on-site or through written agreement;
- 99 | (k) other support services, as necessary, such as physical therapy and rehabilitation medicine;
- 100 | (l) continuous availability of anatomic and clinical pathology and laboratory services including clinical
101 | chemistry, immuno-suppressive drug monitoring and tissue typing;
- 102 | (m) continuous availability of red cells, platelets, and other blood components;
- 103 | (n) an established organ donation protocol, with brain death protocol, consistent with applicable
104 | Michigan law; and
- 105 | (o) a written transplant agreement with Michigan's federally designated OPO to promote organ
106 | donation at the applicant hospital(s).

107
108 | (2) An applicant ~~PROPOSING TO INITIATE must~~ SHALL provide an implementation plan for the
109 proposed transplantation service. Implementation plan means a plan that documents how a proposed
110 transplantation service will be initiated within the SPECIFIED time period ~~specified in these standards or~~
111 ~~the CON Rules. AS APPLICABLE TO THE PROPOSED PROJECT. At a minimum, the~~ The
112 implementation plan shall identify:

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

117 (b) the timetable for completing each component or activity specified in subsection (a); and

118 | (c) ~~if the applicant~~ SHALL DOCUMENT what changes have or will be made to ensure that the
119 proposed service can be initiated and provided on a regular basis; IF previously has been PREVIOUSLY
120 approved for a transplantation service for which either the CON expired or the service did not perform a
121 transplant procedure during any consecutive 12-month period, ~~what changes have or will be made to~~
122 ~~ensure that the proposed service can be initiated and provided on a regular basis.~~

123
124 | (3) An application ~~APPLICANT(S) which proposes~~ PROPOSING TO INITIATE a joint sharing
125 arrangement for a transplantation service ~~which~~ THAT involves more than one licensed site shall
126 demonstrate all of the following:

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

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

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

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

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

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

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

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

145
146 | ~~(4) An applicant shall provide verification of Medicaid participation. An applicant that is a new~~
147 ~~provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided~~
148 ~~to the Department within six (6) months from the offering of services if a CON is approved.~~

149
150 | ~~(54)~~ An application which proposes a joint sharing arrangement for a heart, heart/lung, lung or liver
151 transplantation service which involves more than one licensed site, where the licensed sites in the joint
152 sharing arrangement are not part of a single legal entity authorized to do business in Michigan, shall not
153 be required to meet Section 4(1) or 5(1) of these standards, if an applicant can demonstrate all of the
154 following:

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

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

- 159 (iii) the application contains a formal plan for the sharing of services, staff and administrative
160 functions related to the transplantation service, including but not limited to: patient review, patient
161 selection, donor organ retrieval and patient care management;
- 162 (iv) an applicant has designated a single licensed site where all of the adult transplantation
163 procedures will be performed and a single licensed site where all of the pediatric transplantation
164 procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;
- 165 (v) the licensed site at which the pediatric transplantation service will be provided shall have admitted
166 or discharged at least 7,000 pediatric patients during the most recent 12-month period for which verifiable
167 data are available to the department;
- 168 (vi) the licensed site that is designated as the site at which adult procedures will be performed is
169 authorized under former Part 221 or Part 222, at the time the application is submitted to the Department,
170 to perform adult heart or heart/lung or lung or liver transplantation services;
- 171 (vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation
172 procedures under the same OPTN certification; and
- 173 (viii) the applicant projects a minimum of 12 adult and 10 pediatric heart, heart/lung, lung or liver
174 transplantation procedures in the second 12-months of operation following the date on which the first
175 heart, heart/lung, lung or liver transplant procedure is performed, and annually thereafter.

176
177 **Section 4. Additional requirements for heart, heart/lung or lung transplantation services**
178

179 Sec. 4. (1) Approval of an application proposing to provide heart, heart/lung or lung transplantation
180 services shall not result in more than three (3) heart, heart/lung or lung transplantation services in the
181 planning area. In evaluating compliance with this subsection, an application submitted or a certificate
182 approved pursuant to Section 3(54) of these standards shall be considered as a single service.
183

184 (2) Except for an application pursuant to Section 3(54) of these standards, an applicant for a heart,
185 heart/lung or lung transplantation service shall project a minimum of 12 heart, heart/lung or lung
186 transplantation procedures annually in the second 12-months of operation following the date on which the
187 first heart, heart/lung or lung transplant procedure is performed and annually thereafter.
188

189 (3) An applicant proposing to provide heart, heart/lung or lung transplantation services shall
190 demonstrate that it either operates an existing renal transplant service or has a written agreement with a
191 renal transplant service in the same hospital subarea that ensures that the professional expertise of the
192 renal transplant service is readily available to the proposed transplantation service.
193

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

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

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

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

203 (d) continuously available coagulation laboratory services; and

204 (e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on
205 demand.
206

207 **Section 5. Additional requirements for liver transplantation services**
208

209 Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not
210 result in more than three (3) liver transplantation services in the planning area. In evaluating compliance

211 | with this subsection, an application submitted or a certificate approved pursuant to Section 3(54) of these
212 standards shall be considered as a single service.

213
214 | (2) Except for an application pursuant to Section 3(54) of these standards, an applicant for a liver
215 transplantation service shall project a minimum of 12 liver transplantation procedures annually in the
216 second 12-months of operation following the date on which the first liver transplant procedure is
217 performed, and annually thereafter.

218
219 (3) An applicant proposing to provide liver transplantation services shall demonstrate that it either
220 operates an existing renal transplant service or has a written agreement with a renal transplant service in
221 the same hospital subarea that ensures that the professional expertise of the renal transplant service is
222 readily available to the proposed transplantation service.

223
224 (4) An applicant proposing to provide a liver transplantation service shall demonstrate that it offers all
225 of the following services or programs:

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

234 **SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION**

235
236
237 SEC. 6. An applicant shall provide verification of Medicaid participation. An applicant that is a new
238 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
239 to the Department within six (6) months from the offering of services if a CON is approved.

240 **Section 67. Review standards for comparative reviews**

241
242
243 Sec. 67. ~~(1)~~—Any application subject to comparative review under Section 22229 of the Code, being
244 Section 333.22229 of the Michigan Compiled Laws, ~~or under these standards~~ shall be grouped and
245 reviewed comparatively with other applications ~~in accordance with the CON rules.~~ **FOR PURPOSES OF**
246 **THESE STANDARDS, comparative group means the applications that have been grouped for the same**
247 **type of project in the same planning area and are being reviewed comparatively in accordance with the**
248 **CON rules.**

249
250 **(21) Qualifying project means each application in a comparative group which has been reviewed**
251 **individually and has been determined by the Department to have satisfied all of the requirements of**
252 **Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other**
253 **applicable requirements for approval in the Code and these standards.**

254 **(a)** A qualifying project will be awarded points based on the percent of compliance with the Uniform
255 Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the
256 Michigan Compiled Laws. The number of points awarded shall be calculated by dividing the number of
257 deaths reported to the OPO by the total number of eligible deaths reported to the Department and
258 multiplying the product by 4. The maximum number of points that can be awarded under this subsection
259 is 4. An applicant shall provide, in the application at the time it is submitted to the Department,
260 documentation of the total number of eligible deaths at the licensed site at which the proposed
261 transplantation service will be provided, for the most recent year for which the Department has verifiable
262 data.

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

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

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

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the nearest whole number, is the number of points that will awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total hospital charges expressed as a percentage, rounded to the nearest whole number, as determined by the Michigan Department of Community Health Medical Services Administration. The indigent volume data being used in this subsection is the data in the most current DCH-MSA Disproportionate Share Hospital (DSH) report at the time the application(s) is deemed submitted by the Department.

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

(3) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the application by the CON administrative unit of the Department responsible for administering the CON program when an application is submitted.

(4) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from

316 conflicting information. For example, if submitted information would result in 6 points being awarded, but
317 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the
318 conflicting information does not affect the point value, the Department will award points accordingly. For
319 example, if submitted information would result in 12 points being awarded and other conflicting information
320 would also result in 12 points being awarded, then 12 points will be awarded.

321
322 **Section 78. Project delivery requirements -- terms of approval**

323
324 Sec. 78. ~~(1)~~—An applicant shall agree that, if approved, the HLL service(s) shall be delivered in
325 compliance with the following terms of CON approval:

326
327 (a1) Compliance with these standards. An applicant shall immediately report to the Department any
328 changes in key staff or other aspects of the transplantation service that may affect its ability to comply with
329 these standards.

330
331 ~~_(b2) Compliance with applicable safety and operating standards.~~

332
333 ~~—(c) Compliance with the following quality assurance standardsREQUIREMENTS; as applicable:~~

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

336 ~~(iiA) The applicant shall comply and remain MAINTAIN a functionally active program with~~
337 ~~thePURSUANT TO OPTN and its by-laws and policies.~~

338 ~~(A) The applicant shall comply with the Center for Medicare and Medicaid Services (CMS) standards~~
339 ~~and shall become Medicare approved within THE FIRST five years of implementation.of services.~~

340 ~~(B) The applicant must be in good standing with the OPTN.~~

341 ~~(iiiB) The transplantation service shall have a transplant team leader and coordinator.~~

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

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

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

352 ~~(viiF) The applicant shall establish and maintain an active, formal multi-disciplinary research program~~
353 ~~related to the proposed transplantation service.~~

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

356 ~~(ixH) The applicant shall maintain an organized institutional transplant registry for recording ongoing~~
357 ~~information on its patients being evaluated for transplant. The applicant shall also maintain a registry of~~
358 ~~patients listed for a transplant and for transplant recipients as required by the federal OPTN.~~

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

362 ~~(J) Compliance with the Uniform Anatomical Gift Law, pursuant to MCL Section 333.10101 et seq. of~~
363 ~~the Michigan Compiled Laws.~~

364
365 ~~(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:~~

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

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

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

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

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

376
377 (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

378 —(A)—(x) The applicant shall perform the applicable required volumes within the time periods specified
379 in these standards, and annually thereafter.

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

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

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

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

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

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

398 ~~(xii)C~~ The applicant shall provide the Department with a TIMELY notice stating the date on which the
399 first transplant procedure is performed ~~and such notice shall be submitted to the Department~~ consistent
400 with applicable statute and promulgated rules.

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

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

406 ~~—(d) Compliance with the Uniform Anatomical Gift Law, pursuant to MCL Section 333.10101 et seq. of~~
407 ~~the Michigan Compiled Laws.~~

408
409 (25) The agreements and assurances required by this section, as applicable, shall be in the form of a
410 certification agreed to by the applicant or its authorized agent.

411 412 **Section 89. Documentation of projections**

413
414 Sec. 8. An applicant required to project volumes of service under sections 4 or 5 shall specify how the
415 volume projections were developed. This specification of projections shall include a description of the
416 data source(s) used, assessments of the accuracy of these data and the statistical method used to make
417 the projections. Based on this documentation, the Department shall determine if the projections are
418 reasonable.

419 420 **Section 910. Health Service Areas Effect on prior CON Review Standards; comparative reviews**

421 |
422 | Sec. 11. These CON review standards supersede and replace the CON Review Standards for
423 | Heart/Lung and Liver Transplantation Services approved by the CON Commission on March 25, 2010 and
424 | effective on MAY 28, 2010.

425 |
426 | (1) Projects reviewed under these standards shall be subject to comparative review.
427 |

Counties assigned to each health service area are as follows:

HEALTH SERVICE AREA COUNTIES

Sec. 9. Counties assigned to each of the health service areas are as follows:

<u>HSA</u>		<u>COUNTIES</u>	
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 10. ~~Effect on prior CON Review Standards; comparative reviews~~

~~—Sec. 10. (1) These CON review standards supersede and replace the CON Review Standards for Heart/Lung and Liver Transplantation Services approved by the CON Commission on March 9, 2004 and effective on June 4, 2004.~~

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~~(21) Projects reviewed under these standards shall be subject to comparative review.~~