

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
HEART/LUNG & LIVER TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (HLLSAC) MEETING**

Thursday, October 15, 2009

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

APPROVED MINUTES

I. Call to Order

Chairperson Ball called the meeting to order at 9:05 a.m.

A. Members Present:

Marwan S. Abdoulijoud, MD, Henry Ford Hospital
James F. Ball, Chairperson, Michigan Manufacturers
Wayne Cass, Vice-Chairperson, Coalition of Labor Organizations Michigan State
Heidi Gustine, Munson Medical Center
Jerry Johnson, MD, Blue Cross Blue Shield of Michigan
Alan Koffron, MD, Beaumont Hospitals
Richard E. Pietroski, Gift of Life Michigan
Jeannette Prochazka, Borgess Health
Jeffrey Punch, MD, University of Michigan Health System
John D. Serini, DO, Metro Health Hospital

B. Members Absent:

Frederick R. Armenti, MD, West Michigan Cardiothoracic Surgeons, PLC
Robert L. Hooker, MD, West Michigan Cardiothoracic Surgeons, PLC

C. Michigan Department of Community Health Staff Present:

Jessica Austin
Michael Berrios
Sallie Flanders
Kasi Kelley
Irma Lopez
Andrea Moore
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

No conflicts were noted for the record.

III. Review of Agenda

Motion by Dr. Johnson, seconded by Mr. Pietroski, to accept the agenda as presented.
Motion Carried.

IV. Review of Minutes of September 15, 2009

Motion by Dr. Johnson, seconded by Vice-Chairperson Cass, to accept the minutes as presented.
Motion Carried.

V. Confirmation of SAC position regarding elements 5 a. & b. of the charge.

Chairperson Ball gave a brief overview of the SAC's position regarding the elements of 5 a. & b. of the charge.

Public Comment:

Bob Meeker, Spectrum Health, read for Dr. Hooker (Attachment A)

Discussion followed.

Motion by Vice-Chairperson Cass, seconded by Dr. Johnson, proposal to not separate the state into two.

VI. Final Review of Proposed Language

Ms. Flanders gave the final review of proposed language. (Attachment B)

VII. Public Comment

Bob Meeker, Spectrum Health
Melissa Cupp, Wiener Associates

Discussion followed.

Motion by Dr. Punch, seconded by Dr. Johnson, to accept the proposed language and move forward to commission. Motion Carried.

VIII. Adjournment

Motion by Vice-Chairperson Cass, seconded by Dr. Serini, to adjourn the meeting at 10:11 a.m.
Motion Carried



October 15, 2009

James Ball, Chair
 Heart, Heart-Lung, Liver Standards Advisory Committee
 C/o Michigan Department of Community Health
 Capitol View Building,
 201 Townsend Street
 Lansing, MI 48913

Dear Mr. Ball,

I regret that I am unable to attend today's meeting of the SAC in person, due to a long-standing commitment. However, I want to register my opinions about what I understand to be the main topic of discussion at today's meeting – access to transplant services in outstate Michigan. This is a topic that I feel strongly about, as do my colleagues – cardiac surgeons, cardiologists, and referring physicians – on the western side of the state. In fact, much of the medical community in West Michigan is supportive of this effort, including Michigan State University College of Human Medicine and Van Andel Research Institute. I am concerned that this issue did not receive a full discussion by the SAC, because of the revelation that there is indeed an available program under the existing cap of three (3) programs. The last scheduled meeting of the SAC is not the appropriate time to take up this discussion seriously for the first time.

On July 16, 2009, I presented the case for an additional heart transplant program in western Michigan. To reiterate the main points:

- It is a major hardship for patients to travel hundreds of miles across the state, or out of state, to receive their transplant. Patients and families must uproot their lives, which results in high costs – both emotional and monetary. In addition to long hospital stays (ALOS ~ 40 days), patients are required to remain within 60 minutes of the transplant center for up to six (6) months.
- Long-term continuity of care is difficult, including follow-up treatment with the transplant physician.
- There is strong support for a heart transplant program in western Michigan
- The population of western Michigan is growing faster than the eastern side of the state and is sufficient to support a heart transplant program.
- The numbers of patients in the Spectrum Health Heart Failure Clinic are increasing substantially, as are our referrals for heart transplant.
- Many western Michigan residents are going out of state for their heart transplants; others are going without needed transplants.

Grand Rapids
 Meijer Heart Center, Ste 8830
 100 Michigan St NE, MC 103
 Grand Rapids, MI 49503
 V 616 459.7258
 F 616 459.5215

John C. Heiser, MD
 Edward T. Murphy, MD
 Robert L. Hooker, MD

Lawrence H. Patzelt, MD

Charles L. Wilkies, MD
 Theodore J. Boeve, MD
 Tomasz A. Timek, MD

Muskegon
 1560 E Sherman Blvd
 Ste 309
 Muskegon, MI 49444
 V 231 830.8643
 F 231 830.8651

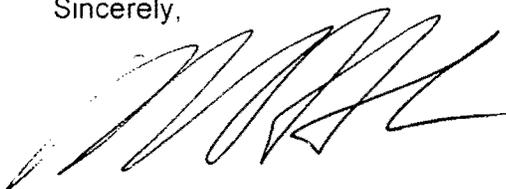
- Spectrum Health has an active organ donation program, which is the largest in the state and one of the largest in the nation.
- West Michigan possesses the capability to develop a transplant program through a coalition of key players – Michigan State University College of Human Medicine, Spectrum Health Meijer Heart Center & Van Andel Research Institute.
- Heart failure patients who live in southeastern Michigan, close to a transplant center, have a much greater chance of receiving a transplant than those who live in other parts of the state.
- Costs for heart surgery are substantially lower in western Michigan than they are in southeastern Michigan.
- Experience in Florida shows that the addition of a new heart transplant program in 2001 did not substantially impact the volumes at existing transplant centers and increased the total number of heart transplants performed in the state, thereby improving access.

These points did not receive adequate attention by the SAC, because of the revelation at that same meeting that the heart transplant programs at Henry Ford and Children's are a single program under a joint sharing agreement. The status of the heart transplant programs at Henry Ford and Children's as a single program under CON was confirmed by MDCH staff at the following meeting, on August 13, 2009. This discovery rendered moot any discussion about the need for another heart transplant program in western Michigan or anywhere else in the state. It also eliminated the main reason that the SAC was convened. I question the appropriateness of making a recommendation about access to transplant on the western side of the state, given the fact that the main premise under which the SAC was convened has been determined to be invalid.

The joint status of the Henry Ford and Children's programs addresses a significant concern I had coming into the SAC deliberations. That is, even under the cap of three (3) programs, there are not currently three (3) full-service heart transplant programs for the residents of the state. To count the program at Children's Hospital as one of the three violates the spirit of the CON requirements. If the other SAC members agree with me and would like to preempt any advice to the contrary by the Attorney General, the CON standards could be revised to state, in Section 4, that: "Approval of an application ... shall not result in more than three (3) **adult** heart, heart/lung or lung transplantation services in the planning area."

Again I regret not being able to attend the meeting in person. I appreciate the time and attention paid to this issue by the SAC.

Sincerely,



Robert L. Hooker, MD

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR HEART/LUNG AND LIVER TRANSPLANTATION SERVICES

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

Section 1. Applicability

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

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

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

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

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

Section 2. Definitions

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

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

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

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

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

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

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

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

155 ~~(IIIC) 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**

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:
 337

Number of Transplant Programs in HSA	Points Awarded
Two or more programs	0
One program	2
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-TOTAL UNCOMPENSATED CARE at the licensed hospital-site at which
 348 the proposed heart/lung or liver 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-TOTAL UNCOMPENSATED CARE, rounded to the nearest whole number, for each licensed
 351 hospital site at which a heart/lung or liver transplantation service is proposed to be provided. Determine
 352 the licensed hospital-site that has the highest indigent volume-TOTAL UNCOMPENSATED CARE in the
 353 same comparative group. Divide the medical/surgical indigent volume-TOTAL UNCOMPENSATED
 354 CARE for that licensed hospital-site by 4.0. The result is the indigent volume-TOTAL UNCOMPENSATED
 355 CARE factor ROUNDED TO THE NEAREST WHOLE NUMBER.

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

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

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

372 existing heart/lung or liver transplantation service, and submits documentation from the existing
 373 heart/lung or liver transplantation service(s) of these referrals.

374
 375 (3) Each application in a comparative review group shall be individually reviewed to determine
 376 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
 377 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the
 378 Code and these standards. If the Department determines that one or more of the competing applications
 379 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
 380 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
 381 defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have
 382 the highest number of points when the results of subsection (2) are totaled. If two or more qualifying
 383 projects are determined to have an identical number of points, the Department shall approve those
 384 qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the
 385 Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications
 386 were received by the Department, based on the date and time stamp placed on the application for BY
 387 THE CON form (form T-150-G-1.01 or any subsequent replacement form) by the Division of Health
 388 Facility Development (or the administrative unit of the Department responsible for administering the CON
 389 program) when an application is submitted.

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

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

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

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

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

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

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

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

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

421 (B) THE APPLICANT MUST BE IN GOOD STANDING WITH THE ORGAN PROCUREMENT AND
 422 TRANSPLANTATION NETWORK (OPTN).

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

424 (iv) The applicant shall have patient management plans and protocols that include the following: (A)

425 therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient
 426 management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the
 427 service; and (C) long-term management and evaluation, including education of the patient, liaison with
 428 the patient's attending physician, and the maintenance of active patient records for at least 5 years.

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

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

434 (vii) The applicant shall establish and maintain an active, formal multi-disciplinary research program
 435 related to the proposed transplantation service.

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

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

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

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

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

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

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

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

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

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

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

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

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

476
 477 ~~Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver~~

478 **transplantation services**

479
 480 ~~Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:~~
 481 ~~(a) a written agreement with the federally approved organ procurement organization whose~~
 482 ~~designated service area includes the location of the proposed transplantation service;~~
 483 ~~(b) organ preservation capability;~~
 484 ~~(c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;~~
 485 ~~(d) an organized 24-hour communication service capable of serving the transplant team and others,~~
 486 ~~as appropriate;~~
 487 ~~(e) a cyclosporine assay laboratory with results available on the same day;~~
 488 ~~(f) an immunologic monitoring laboratory;~~
 489 ~~(g) a specialized inpatient transplantation unit;~~
 490 ~~(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in~~
 491 ~~conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient~~
 492 ~~and managing immuno-suppressed patients.~~
 493 ~~(i) a medical staff and governing board policy that provides for the selection of candidates for organ~~
 494 ~~transplantation procedures in accordance with the patient selection criteria approved by the Department;~~
 495 ~~(j) an ethics committee or human use committee to review and approve the institution's protocols~~
 496 ~~related to organ transplantation, including protocols involving the selection of donors and recipients; and~~
 497 ~~(k) a multi-disciplinary transplant recipient evaluation committee.~~

498
 499 ~~(2) An applicant shall agree that the transplantation service shall be staffed with qualified adult and~~
 500 ~~pediatric, as applicable, transplant surgeon(s) and transplant physician(s). For purposes of evaluating~~
 501 ~~this subsection, the Department shall consider it prima facie evidence as to the training of the surgeon(s)~~
 502 ~~and physician(s) if they meet the requirements for certification by Medicare or the OPTN. However, the~~
 503 ~~applicant may submit and the Department may accept other evidence that the surgeon(s) and~~
 504 ~~physician(s) are qualified.~~

505
506 **Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung**
507 **transplantation services**

508
 509 ~~Sec. 9. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be~~
 510 ~~staffed and provided by at least the following:~~
 511 ~~(a) cardiologists or surgeons trained in endocardial biopsy;~~
 512 ~~(b) cardiologists and surgeons trained in immunosuppression techniques;~~
 513 ~~(c) both adult and pediatric, as appropriate, cardiologists and surgeons;~~
 514 ~~(d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants~~
 515 ~~in animals in a setting simulating the human situation;~~
 516 ~~(e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with~~
 517 ~~one surgical team continuously available for organ retrieval thereby enabling a second team to~~
 518 ~~simultaneously begin performing a recipient operation;~~
 519 ~~(f) a pathologist capable of diagnosing rejection on endocardial biopsies; and~~
 520 ~~(g) an anesthesiologist trained in open heart surgery.~~

521 ~~(2) An applicant must demonstrate heart transplant patient survival rates at one year and two years~~
 522 ~~after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must~~
 523 ~~demonstrate patient survival rates at one and two years after transplantation of no less than the national~~
 524 ~~average survival rate for the specific transplant type for the most recent year for which data is published~~
 525 ~~by the OPTN.~~

526
527 **Section 10. Additional terms of approval -- applicants proposing liver transplantation services**

528
 529 ~~Sec. 10. (1) An applicant shall agree that the liver transplantation service will be staffed and provided~~
 530 ~~by at least the following:~~

- 531 ~~— (a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals~~
532 ~~in a setting simulating the human situation;~~
533 ~~— (b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy,~~
534 ~~repair of biliary strictures, and Porto systemic shunts;~~
535 ~~— (c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical~~
536 ~~staff;~~
537 ~~— (d) a pathologist capable of diagnosing hepatic rejection;~~
538 ~~— (e) anesthesiologist(s) trained in liver transplantation;~~
539 ~~— (f) two liver transplant surgical teams, with one surgical team continuously available for organ~~
540 ~~retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in~~
541 ~~preparation for liver implantation; and~~
542 ~~— (g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available~~
543 ~~for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement~~
544 ~~which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver~~
545 ~~transplant recipient operation; and, a veno-venous bypass system which does not require heparin;~~
546
547 ~~— (2) The applicant shall establish and maintain all of the following:~~
548 ~~— (a) nuclear HID biliary scan availability;~~
549 ~~— (b) a continuously available coagulation laboratory; and~~
550 ~~— (c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of~~
551 ~~plasma on demand.~~
552
553 ~~— (3) An applicant must demonstrate patient survival rates at one year and two years after~~
554 ~~transplantation of no less than the national average survival rate for the most recent year for which data is~~
555 ~~published by the OPTN.~~

556 **Section 418. Documentation of projections**

557
558
559 ~~Sec. 418. An applicant required to project volumes of service under sections 4 or 5 shall specify how~~
560 ~~the volume projections were developed. This specification of projections shall include a description of the~~
561 ~~data source(s) used, assessments of the accuracy of these data and the statistical method used to make~~
562 ~~the projections. Based on this documentation, the Department shall determine if the projections are~~
563 ~~reasonable.~~

Section 429. Health Service Areas**Sec. 429. 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 4310. Effect on prior CON Review Standards; comparative reviews

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

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