

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

Thursday, July 16, 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 9:03 a.m.

**A. Members Present:**

Marwan S. Abdoulijoud, MD, Henry Ford Hospital  
James F. Ball, Chairperson, Michigan Manufacturers  
Robert L. Hooker, MD, West Michigan Cardiothoracic Surgeons, PLC  
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  
Wayne Cass, Vice-Chairperson, Coalition of Labor Organizations Michigan State  
Heidi Gustine, Munson Medical Center

**C. Michigan Department of Community Health Staff Present:**

Jessica Austin  
Kasi Kelley  
Joette Laseur  
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 June 25, 2009**

Motion by Dr. Koffron, seconded by Dr. Punch, to accept the minutes as presented.  
Motion Carried.

**V. The Need for Solid Organ Transplant Services in Western Michigan Presentation**

Dr. Hooker provided an oral and written presentation (Attachment A).

Discussion followed.

Public Comment:  
Bob Meeker, Spectrum Health

Break from 10:44 a.m. to 11:03 a.m.

**VI. Discussion of Access and Technical Language Changes Presentation**

Ms. Rogers gave review of technical language (Attachment B) changes that the department is recommending.

Discussion followed.

Public Comment:  
Bob Meeker, Spectrum Health

**VII. Next Steps**

Dr. Abdouljoud will provide at the next meeting the proposed Liver Language/Requirements.

Dr. Hooker and Dr. Punch will provide at the next meeting the proposed Heart/Lung Language/Requirements.

DCH will provide an update of joint sharing language, and separate requirements for Pediatric and Adult program concepts.

**VIII. Future Meeting Dates**

August 13, 2009  
September 15, 2009  
October 15, 2009

**IX. Public Comment**

No public comments.

**X. Adjournment**

Motion by Dr. Johnson, seconded by Dr. Hooker, to adjourn the meeting at 12:27 p.m. Motion Carried.





Attachment A



# West Michigan Collaborative for Transplant Services

Robert Hooker, M.D.  
West Michigan Cardiothoracic Surgery  
Associate Clinical Professor of Surgery, MSU

July 16, 2009

# Community Support

## Strong community leadership exists in support of the effort to address access to transplant services in western Michigan

Grand Rapids Press  
Grand Valley State University  
Michigan State University Medical School  
Meijer  
C & H Holdings – Cook Holdings  
Warner, Norcross & Judd  
Hauenstein Neurological Center  
Fifth Third Bank  
Michigan Medical, P.C.  
Grand Rapids Mayor Heartwell  
Van Andel Institute (Craig Webb, Ph.D.)  
Lakeland HealthCare  
Oaklawn Hospital  
Pennock Health  
J.C. Huizenga  
West Michigan Cardio-Thoracic Surgeons  
Steelcase  
RDV Corporation (Richard DeVos)  
Mercy Health Partners  
Spectrum Health Reed City  
Anesthesia Medical Consultants

Holland Hospital  
Helen DeVos Children's  
Hospital  
The Right Place, Inc.  
Gerber Memorial Health  
Services  
David G. Frey  
Calvin College (Gaylen J.  
Byker)

### State Senators

Bill Hardiman  
Wayne Kuipers  
Mark Jansen

### State Representatives:

Bill Huizenga  
Dave Hildenbrand  
Kevin Green  
Brian Calley  
Arlan Meekhof  
Dave Agema  
Pete Hoekstra



# Western Michigan Position:

Revise the CON Standards for transplant services in 2009 to allow access by residents of the western part of Michigan



# The Medical Mile





# West Michigan Cardiothoracic Surgeons

- Eight Experienced Cardiothoracic Surgeons – Perform 1400 Open Surgeries Annually
- Certified by the American Board of Thoracic Surgery
- Newest Advancements in:
  - Robotic Heart Surgery
  - Ventricular Assist Device
  - VATS Lobectomy & Robotic Lobectomy
  - Thoracic Aortic Endografting

# West Michigan Heart

- West Michigan Heart Employs over 25 Board Certified Cardiologists
- Treat Multiple Cardiac Conditions Including:
  - Congestive Heart Failure
  - Peripheral Vascular Disease
  - Heart Rhythm Disorders
  - Coronary Artery Disease
  - Congenital Heart Defects
  - Transplant Patients



Attachment A



SPECTRUM HEALTH



# Michigan State Medical School



# Fred and Lena Meijer Heart Center



- 9 State of the Art Operating Rooms
- 8 Cardiac Cath Labs – Over 14,000 procedures done annually
- Superior Post-Operative Care Of VAD, Open Heart and Cardiac Cath Patients on the Meijer Heart Center Inpatient Units



# Van Andel Research Institute

## RECRUITMENT

With the completion of the Van Andel Institute's Phase II, 240,000 additional square feet will be added, tripling lab space. When operating at capacity, VAI expects to employ 800. Van Andel Research Institute recruitment planning is underway and, inherent to that planning are strategic alliances that position VARI discoveries into clinical settings.

## VARI GENOMICS

Personalized therapeutics based on genomic discoveries in individual cancer specimens.

Novel therapeutic targets in orthopedics, neurological disorders and metabolic syndromes based on genomic and epigenetic discoveries.

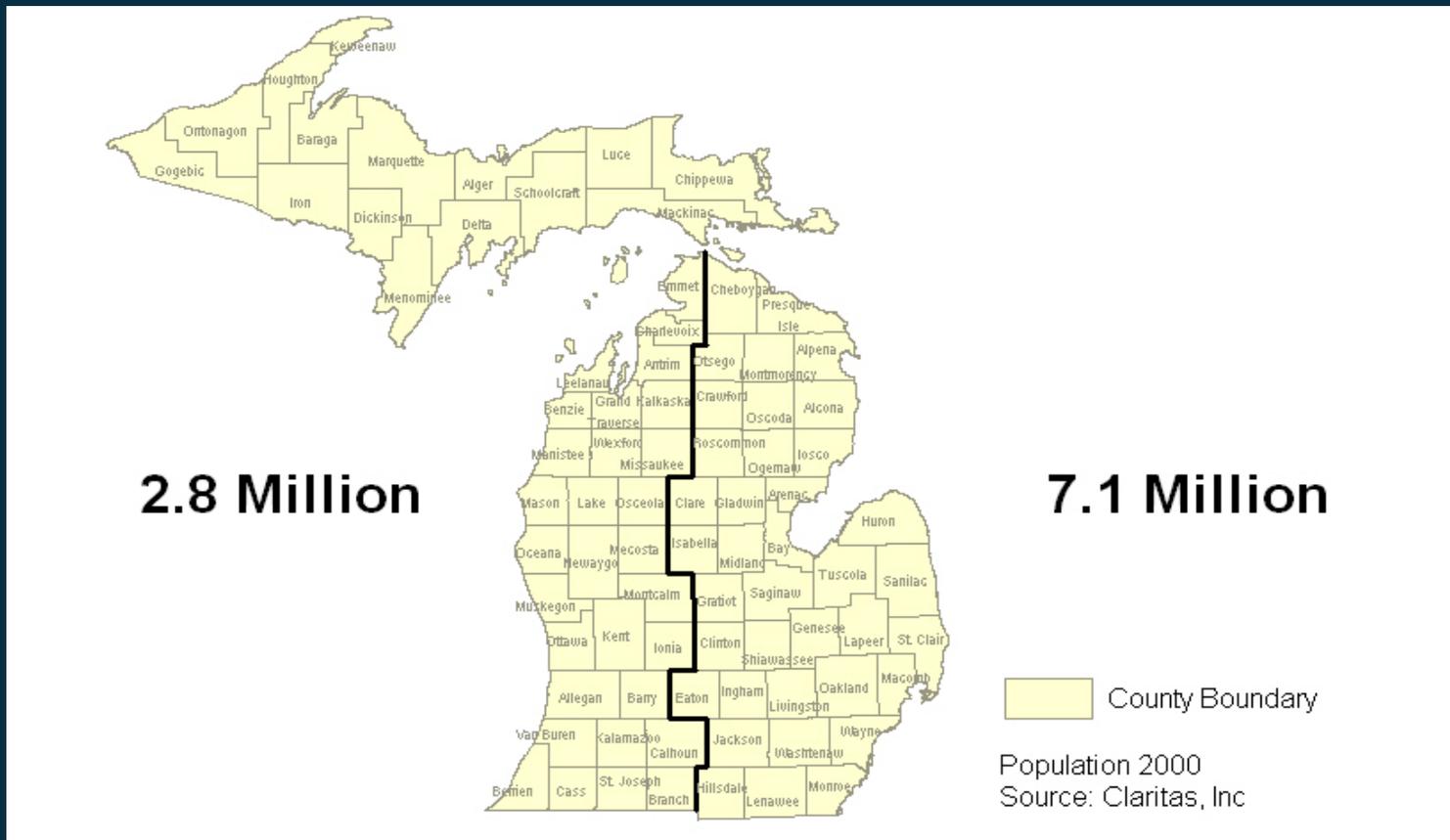
Implementation of genetically engineered laboratory models for drug discovery and development.





# Population

Western Michigan Has More than a Quarter of the State's Population







# Heart Failure Patients: More and Older

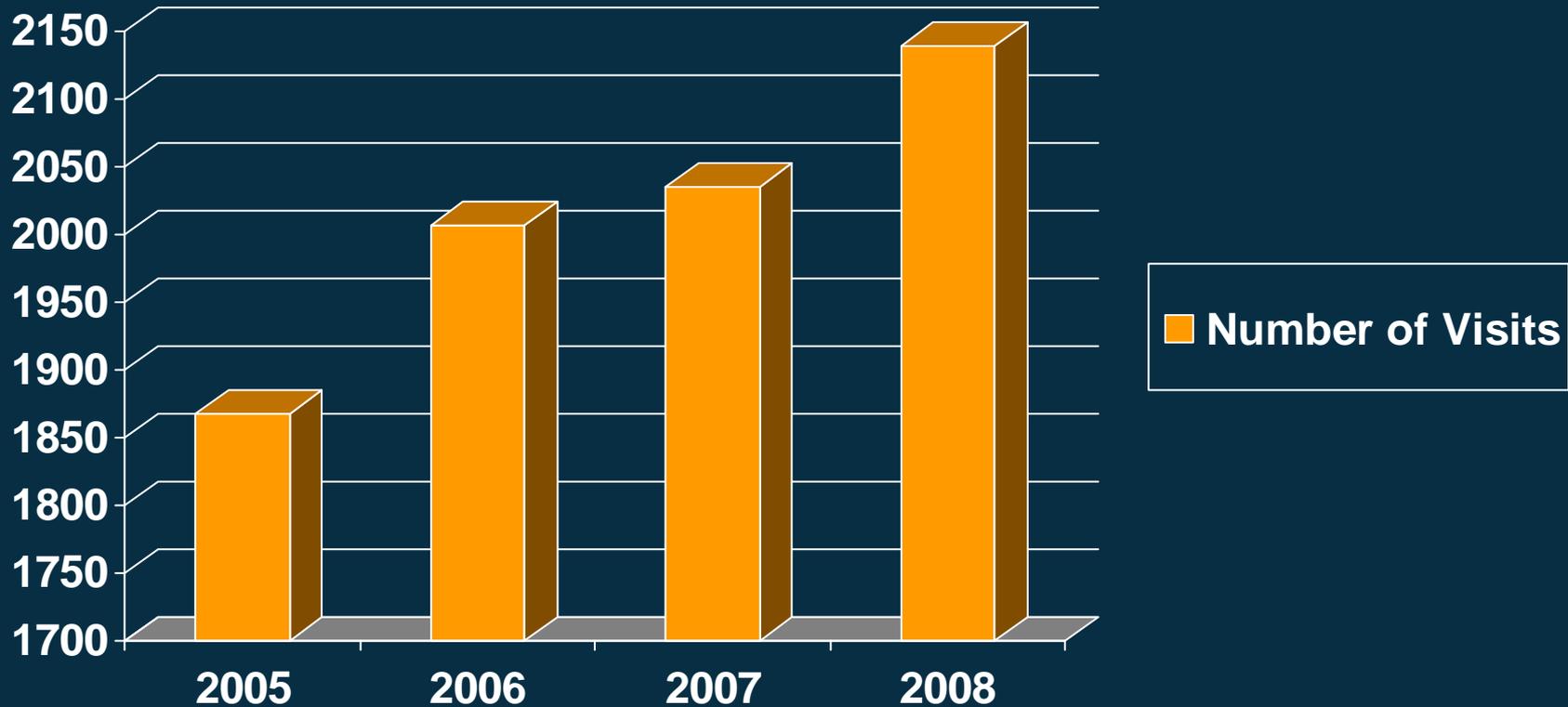
The number of patients age 65 and older who are hospitalized for heart failure has doubled since 1980.

The number of heart failure hospitalizations increased by 131% since 1980

(<http://www.advisory.com>, Daily Briefing, 11/10/2008)



# Patient Volumes at our Heart Failure Clinic





# Heart Failure and Transplant Clinic

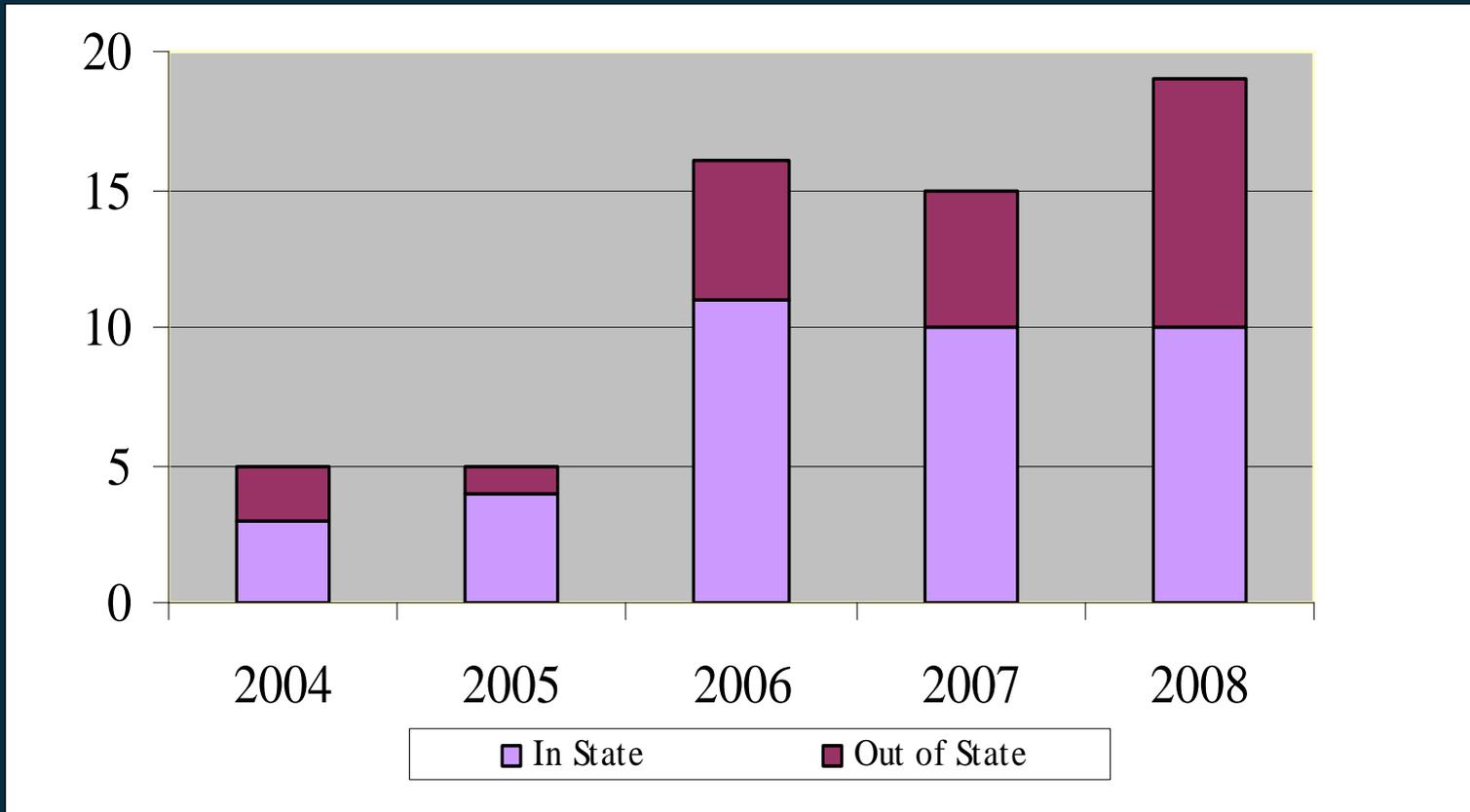
## VAD Patients

Following 11 Patients

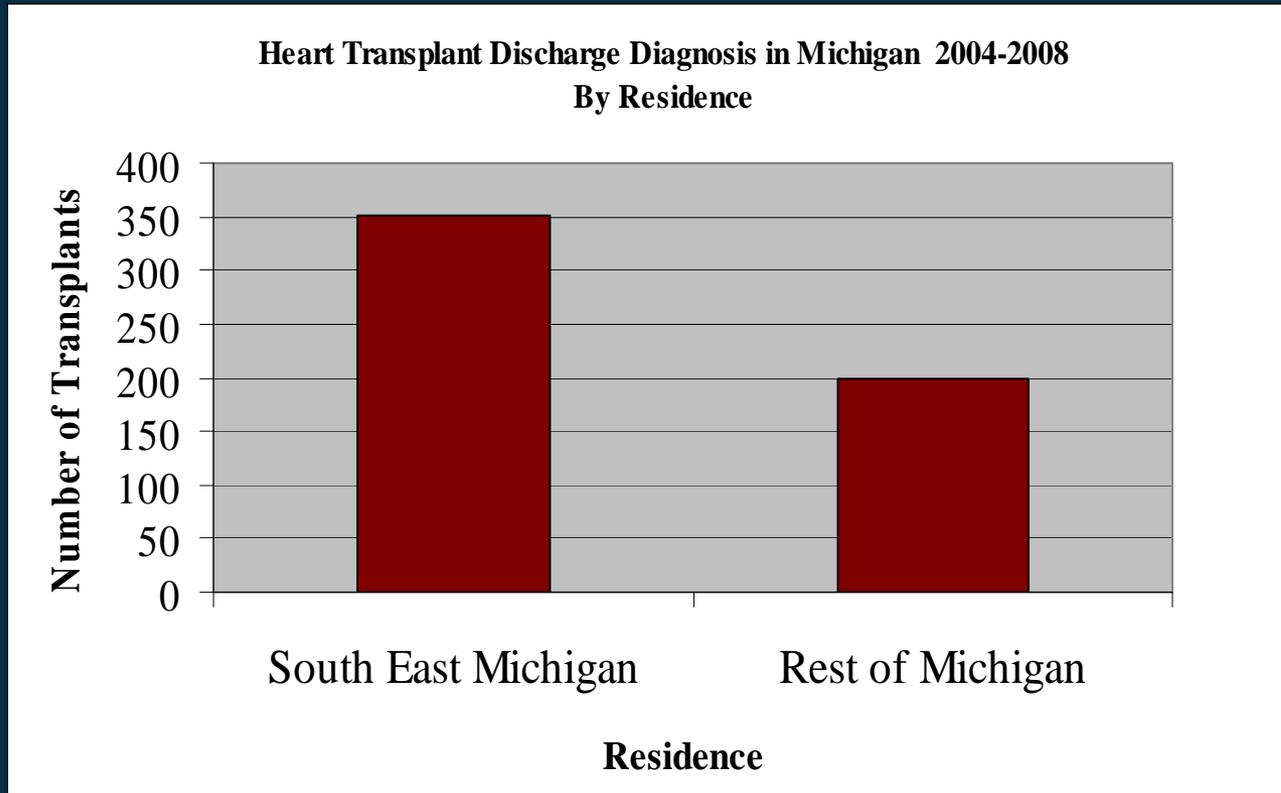
## Transplant Patients

Following approximately 50 transplant Patients

# Spectrum Health Referrals for Heart Transplant



# Proximity to Transplant Center Increases Access



Residents of out-state Michigan receive heart transplants at 2/3 the rate of S.E. Michigan



Attachment A



Van Andel Institute



SPECTRUM HEALTH



# Quality and Volumes at Spectrum Health

The Society for Thoracic Surgeons data has shown that Spectrum Health is among the highest in quality outcomes in the nation.



# Quality Outcomes -

| Calendar Year 2007                                |     |                    |
|---|-----|--------------------|
|   |     | Hospital Mortality |
|   | N   | O/E                |
| Isolated CABG                                     | 544 | 0.4                |
| Isolated Aortic Valve Repair                      | 67  | 0                  |
| CABG+ Aortic Valve Replacement                    | 71  | 0.66               |
| Isolated Mitral Valve Replacement                 | 17  | 0                  |
| CABG+Mitral Valve Replacement                     | 4   | 0                  |
| Isolated Mitral Repair                            | 32  | 0                  |
|   |     |                    |
| deaths in hospital or within 30 days of operation |     |                    |



# Health Grades 2009 – Coronary Bypass Surgery

| <u>Hospital's Name</u> | In hospital Mortality<br>(Survival) | In hospital +1 Month<br>(Recovery +30) | In hospital +6 Months<br>(Recovery +180) |
|------------------------|-------------------------------------|--|--|
| Spectrum Health        | *****                               | *****                                  | *****                                    |
| Henry Ford Hospital    | ***                                 | ***                                    | *  |
| University of Michigan | ***                                 | ***                                    | ***                                      |

Best \*\*\*\*\* As Expected \*\*\*

Poor \*



# Health Grades 2009 – Valve Surgery

| <u>Hospital's Name</u> | InHospital Mortality<br>(Survival) | Inhospital +1 Month<br>(Recovery +30) | Inhospital +6 Months<br>(Recovery +180) |
|------------------------|------------------------------------|---------------------------------------|---|
| Spectrum Health        | *****                              | *****                                 | *****                                   |
| Henry Ford Hospital    | *                                  | *                                     | *                                       |
| University of Michigan | ***                                | ***                                   | ***                                     |
|                        | Best *****                         | As Expected ***                       | Poor *                                  |

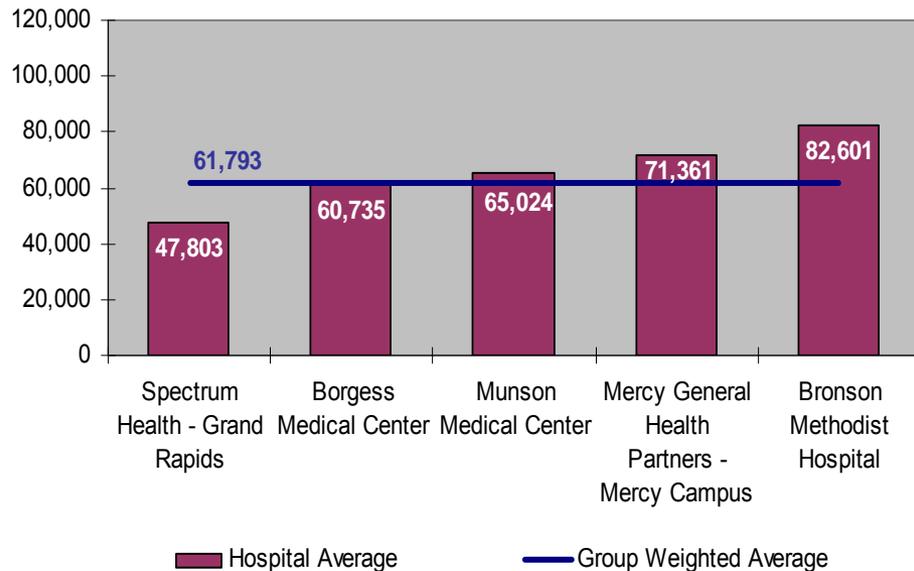
# Value and Cost

- Consistently lower cost and higher quality
- Thomson Benchmarking (12/31/08)
  - Lowest in net revenue
  - Lowest in operating expenses

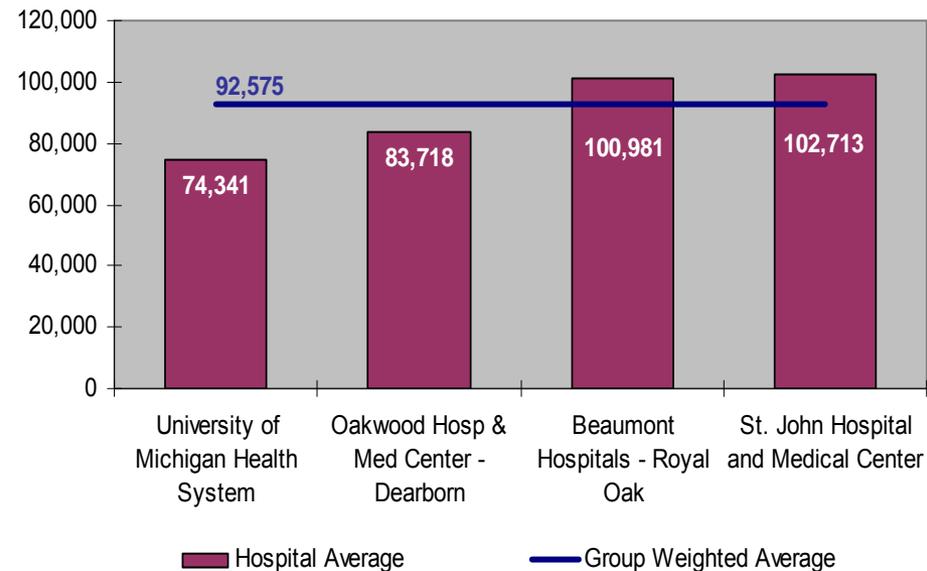
Compared to teaching hospitals providing Level 1 trauma care with 600+ occupied beds and CMI greater than 1.4

# West Michigan Hospitals have Lower Healthcare Charges for Heart Surgery

CABG Charges- Western Michigan Hospitals



CABG Charges- Eastern Michigan Hospitals





Attachment A



SPECTRUM HEALTH



# UNOS Certification

Spectrum Health is certified by UNOS  
for organ transplant.



# CON Requirements for Heart Transplant

- Fully-functioning surgical program; > 300 adult open-heart surgeries a year
- Cardiac catheterization lab; > 500 adult caths a year & angiography
- 24-hour ICU
- Laboratory Services
  - Microbiology & virology
  - Histocompatibility
  - Immunosuppressive drug monitoring
  - clinical chemistry
  - Coagulation lab
  - Tissue typing



# CON Requirements for Heart Transplant

- Available sub specialists
  - Pulmonary
  - Cardiology
  - Gastroenterology
  - Nephrology
  - Immunology
  - Infectious disease
- Supportive rehabilitative and therapy services
- Organ donation protocol
- Agreement with Organ Procurement



# CON Requirements for Heart Transplant

- Full range of diagnostic imaging
- Blood bank capable of 20 units of blood, platelets, and blood products on demand
- Kidney Dialysis & Renal transplant
- Social work & psychiatry
- Clinical research



# Project Delivery Requirements for Heart Transplant

- Two transplant surgical teams
- Three trained cardiac surgeons
- Trained transplant surgeons
- Physicians trained in immuno-suppression techniques
- Surgeons with experience in orthotopic cardiac transplants in animals
- Physicians trained in endocardial biopsy
- Pathologist capable of diagnosing rejection on endocardial biopsies
- Anesthesiologist trained in open-heart surgery



# Project Delivery Requirements for Heart Transplant

- Compliance with OPTN & Medicare
- Transplant team leader & coordinator
- Patient management plans, including
  - Pre procedure
  - Acute care
  - Post discharge
  - Long-term management
- Staff education program
- Community education program
- Multi-disciplinary research program



# Project Delivery Requirements for Heart Transplant

- Nurses trained to care for transplant patients
- In-Patient transplant Unit
- Patient selection policy approved by Medical Staff and Board
- Ethics Committee
- Multi-disciplinary transplant recipient evaluation committee



# Project Delivery Requirements for Heart Transplant

- Transplant registry
- Agreement with OPO
- Organ preservation
- 24-hour transport service
- 24-hour communication service
- Cyclosporine assay lab
- Immunologic monitoring lab

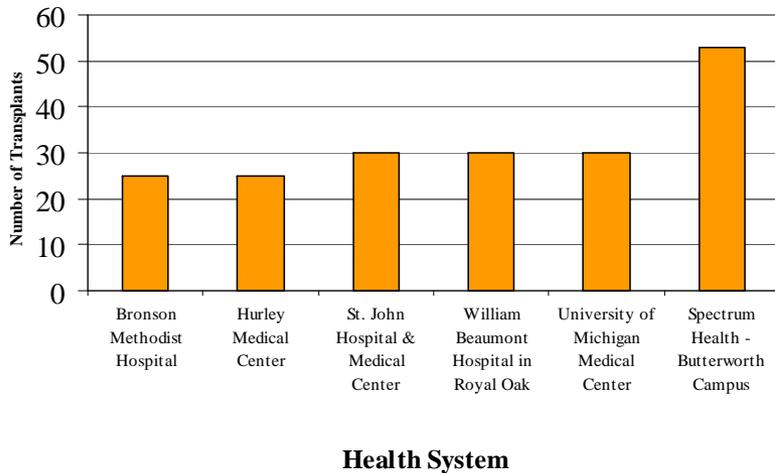


# Community Infrastructure

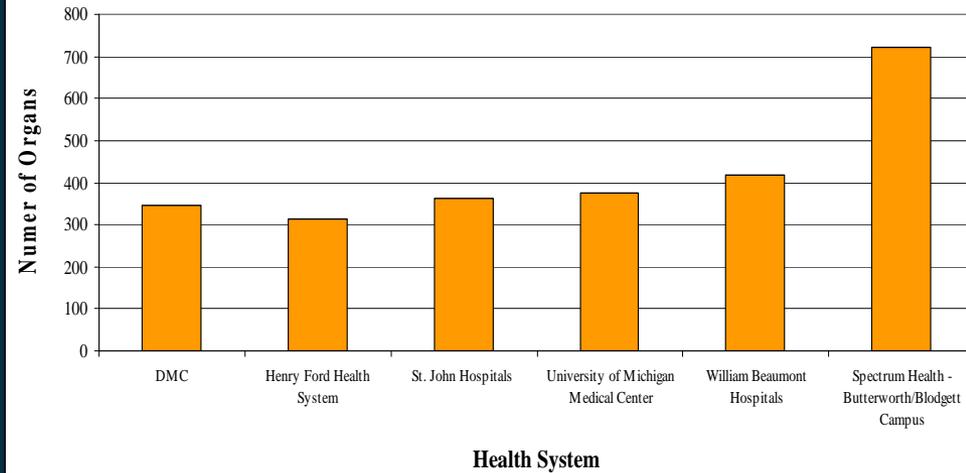
- Van Andel Institute
- Michigan State University College of Human Medicine
- Health Professional Training Programs:
  - Grand Valley State University
  - Hope College
  - Calvin College
  - Aquinas College
  - Ferris State University
  - Western Michigan University
- Rennucci Hospitality House
- Ronald McDonald House

# Gift of Life Donations

### Hearts Donated 2004-2008



### All Organs Donated 2004-2008





# Lung Transplant

Pulmonary Patients in the Grand Rapids area.

- Approximately 25 patients referred for lung transplants in 2008
- 7 patients had a lung transplant
- 12 patients were unable to travel to undergo a transplant; mostly for financial reasons
- Approximately 35 patients currently under treatment for cystic fibrosis; expected to increase to 50 patients by 2010



# Patient Hardship

Average Length of Stay for organ transplant approximately 40 days; patients required to remain within 60 minutes of transplant center for 6 months

Patients and families must uproot their lives

Long Distance Travel for treatment

High costs – both emotional and monetary

Difficult follow-up treatment with transplant physician



# Continuity of Care

## Physician Relationships

### Knowledge of Patient's

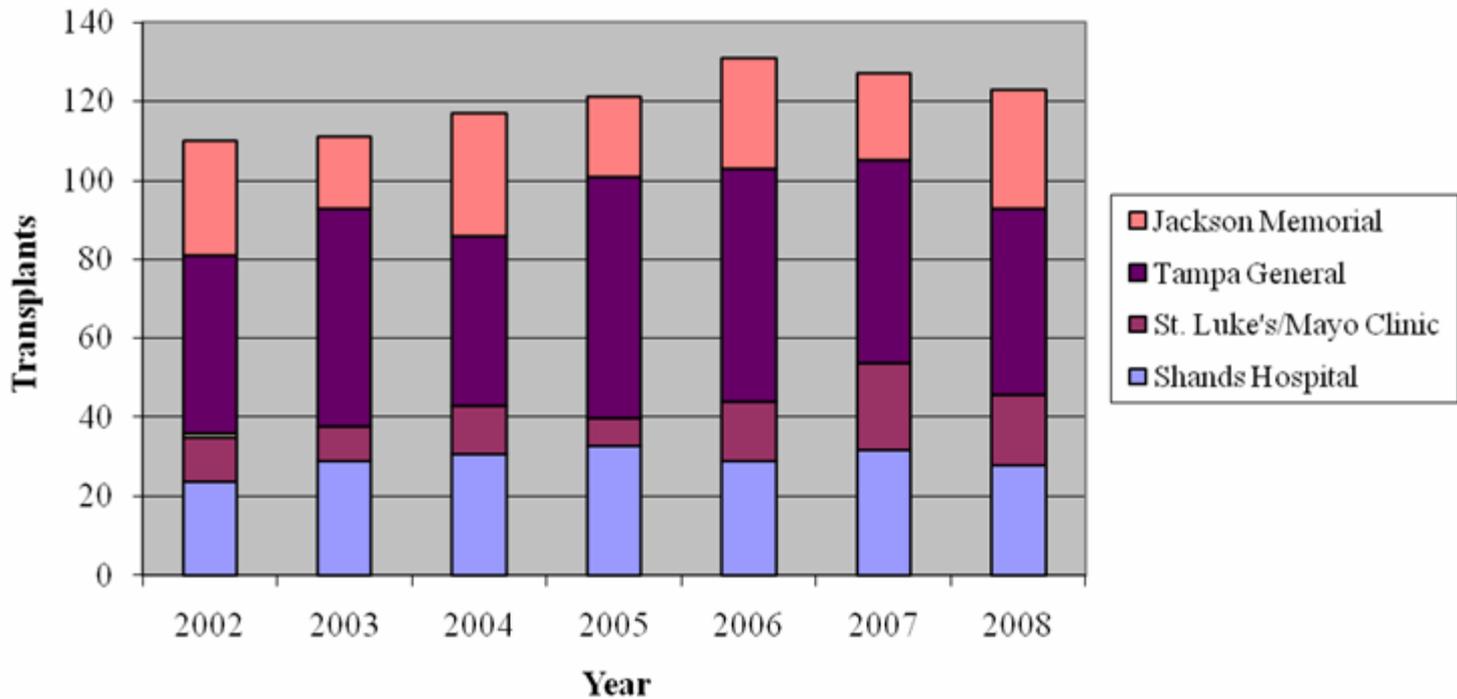
- Disease
- Psycho-social needs
- Co-morbidities
- Management of non-transplant care

### Management of post transplant complications

- Transplant Rejection
- Recurrence

# Florida Transplant Experience

## Heart Transplants in Florida, 2002-2008

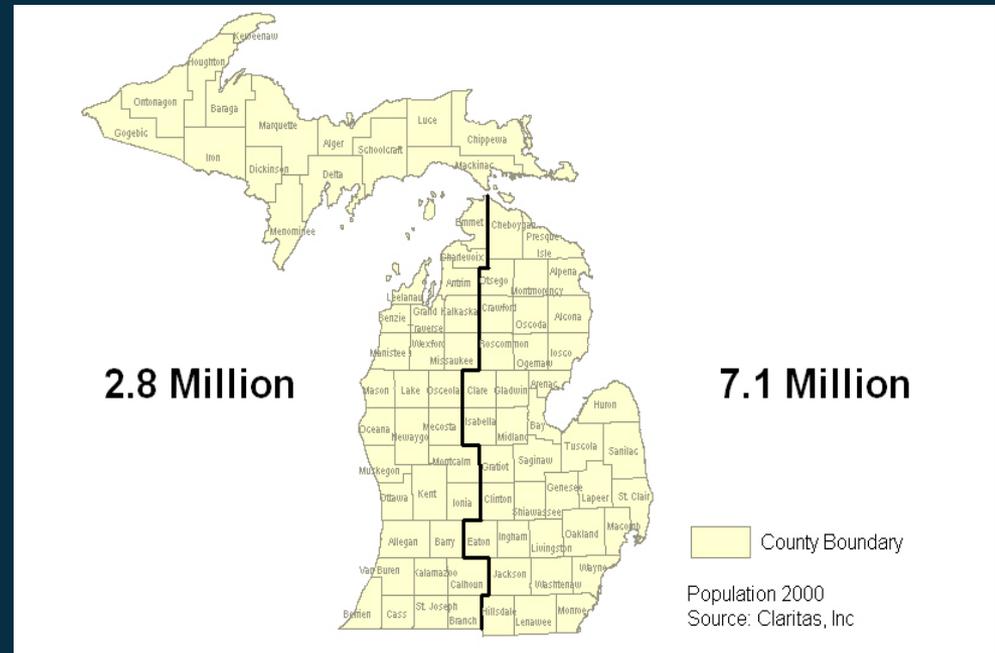


# Proposed CON Solution

Divide Michigan into two (2) planning areas – east and west

Use planning area definitions currently in place for pediatric BMT

Allow at least one (1) heart/lung transplant program in western Michigan





# Say "YES" to Michigan!



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 22 OF THE CODE, HEART/LUNG AND LIVER TRANSPLANTATION IS A COVERED CLINICAL SERVICE. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 222225(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 12.

~~(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 TITLE 42, PART 485.302.~~

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

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

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

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

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

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

107 | active on the date an application is submitted to the Department having accepted potential transplant  
108 | recipient(s) into the program.

109  
110 (2) The definitions of Part 222 shall apply to these standards.

111  
112 | **Section 3. Requirements for approval— all applicants**

113  
114 Sec. 3. (1) An applicant proposing to perform either a heart, heart/lung, or lung or liver transplantation  
115 service shall demonstrate that it offers all of the following services or programs:

- 116 (a) operating rooms;
- 117 (b) anesthesiology;
- 118 (c) microbiology and virology laboratory;
- 119 (d) continuous availability, either on-site or on-call, of:
- 120 (i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear  
121 medicine; and

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

- 125 (e) dialysis;
- 126 (f) infectious disease;
- 127 (g) inpatient-outpatient social work;
- 128 (h) inpatient-outpatient psychiatry/psychology;
- 129 (i) clinical research;
- 130 (j) a histocompatibility laboratory that meets the standards of the American Society for  
131 Histocompatibility and Immunogenetics or an equivalent organization, either on-site or through written  
132 agreement;
- 133 (k) other support services, as necessary, such as physical therapy and rehabilitation medicine;
- 134 (l) continuous availability of anatomic and clinical pathology and laboratory services including  
135 clinical chemistry, immuno-suppressive drug monitoring and tissue typing;
- 136 (m) continuous availability of red cells, platelets, and other blood components;
- 137 (n) an established organ donation protocol, with brain death protocol, consistent with applicable  
138 Michigan law; and

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

141  
142 | (2) An applicant must provide, ~~at the time the CON application is submitted,~~ an implementation plan  
143 for the proposed transplantation service. IMPLEMENTATION PLAN MEANS A PLAN THAT  
144 DOCUMENTS HOW A PROPOSED TRANSPLANTATION SERVICE WILL BE INITIATED WITHIN THE  
145 TIME PERIOD SPECIFIED IN THESE STANDARDS OR THE CON RULES. AT A MINIMUM, THE  
146 IMPLEMENTATION PLAN SHALL IDENTIFY:

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

152 | (IIB) THE TIME TABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN  
153 SUBSECTION (I); AND

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

- 160  
161 (3) An application which proposes a joint sharing arrangement for a transplantation service which  
162 involves more than one licensed site shall demonstrate all of the following:  
163 (a) all licensed sites in the joint sharing arrangement are part of a single legal entity authorized to do  
164 business in Michigan;  
165 (b) all licensed sites in the joint sharing arrangement are geographically close enough so as to  
166 facilitate cost-effective sharing of resources;  
167 (c) an applicant has designated a single licensed site where the transplant surgical procedure(s) will  
168 be performed, except that where an applicant proposes a joint sharing arrangement which involves both  
169 adult and pediatric transplant procedures, the applicant may designate a single licensed site where all  
170 adult transplant procedures will be performed and a single licensed site where all pediatric transplant  
171 procedures will be performed, if:  
172 (i) both licensed sites are part of the joint sharing arrangement;  
173 (ii) the same transplant coordinator will serve patients at both licensed sites;  
174 (iii) laboratory procedures related to the proposed transplantation service will be performed at a  
175 single common laboratory operated by the applicant;  
176 (iv) all physicians performing the proposed transplantation procedures at either licensed site are part  
177 of a common organizational entity (i.e., partnership, professional corporation, or medical school faculty);  
178 and  
179 (v) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation  
180 procedures under the same OPTN certification.

181  
182 (4) An applicant shall provide verification of Medicaid participation. AN APPLICANT THAT IS A  
183 NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF  
184 MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS  
185 FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. at the time the application is  
186 submitted to the Department. ~~If the required documentation is not submitted with the application on the~~  
187 ~~designated application date, the application will be deemed filed on the first applicable designated~~  
188 ~~application date after all required documentation is received by the Department.~~

189  
190 **Section 4. Additional requirements for ~~applicants seeking approval to provide heart or heart/lung~~**  
191 **or lung transplantation services**  
192

193 Sec. 4. (1) Approval of an application proposing to provide heart or heart/lung or lung transplantation  
194 services shall not result in more than three (3) heart or heart/lung or lung transplantation services in the  
195 planning area. In evaluating compliance with this subsection, an application submitted or a certificate  
196 approved pursuant to Section 4(5) of these standards shall be considered as a single service.  
197

198 (2) Except for an application pursuant to Section 4(5) of these standards, an applicant for a heart or  
199 heart/lung or lung transplantation service shall project a minimum of 12 heart or heart/lung or lung  
200 transplantation procedures annually in the second 12-months of operation following the date on which the  
201 first heart or heart/lung or lung transplant procedure is performed and annually thereafter.  
202

203 (3) An applicant proposing to provide heart or heart/lung or lung transplantation services shall  
204 demonstrate that it either operates an existing renal transplant service or has a written agreement with a  
205 renal transplant service in the same hospital subarea that ensures that the professional expertise of the  
206 renal transplant service is readily available to the proposed transplantation service.  
207

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

- 210 (a) a cardiovascular medical/surgical program that includes at least the following: (i) an open heart  
211 surgery service that performs at least 300 adult and/or 100 pediatric procedures annually, as applicable;  
212 and (ii) a cardiac catheterization service that performs at least 500 adult and/or 250 pediatric cardiac

213 catheterizations and coronary arteriograms annually, as applicable, and has the capability to perform  
214 these procedures on an emergency basis.

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

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

217 (d) continuously available coagulation laboratory services; and

218 (e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on  
219 demand.

220

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

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

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

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

232 (iv) an applicant has designated a single licensed site where all of the adult transplantation  
233 procedures will be performed and a single licensed site where all of the pediatric transplantation  
234 procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;

235 (v) the licensed site at which the pediatric transplantation service will be provided shall have  
236 admitted or discharged at least 7,000 pediatric patients during the most recent 12-month period for which  
237 verifiable data are available to the Department;

238 (vi) the licensed site that is designated as the site at which adult procedures will be performed is  
239 authorized under former Part 221 or Part 222, at the time the application is submitted to the Department,  
240 to perform adult heart or heart/lung or lung transplantation services;

241 (vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation  
242 procedures under the same OPTN certification; and

243 (viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung  
244 transplantation procedures in the second 12-months of operation following the date on which the first  
245 heart or heart/lung or lung transplant procedure is performed, and annually thereafter.

246

247 | **Section 5. Additional requirements for applicants seeking approval to provide liver**  
248 **transplantation services**

249

250 Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not  
251 result in more than three (3) liver transplantation services in the planning area.

252

253 (2) An applicant for a liver transplantation service shall project a minimum of 12 liver transplantation  
254 procedures annually in the second 12-months of operation following the date on which the first liver  
255 transplant procedure is performed, and annually thereafter.

256

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

261

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

264 (a) continuous availability, either on-site or on-call, of angiography services;

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

- 266 (c) endoscopic retrograde cholangiopancreatography (ERCP) availability;
- 267 (d) percutaneous cholangiogram availability;
- 268 (e) percutaneous liver biopsy capability;
- 269 (f) a rapid blood infusion system;
- 270 (g) hemoperfusion; and
- 271 (h) a rapid red blood cell (RBC) blood saver system.

272  
 273 **Section 6. REVIEW STANDARDS FOR Additional requirements for applications included in**  
 274 **comparative reviews**

275  
 276 Sec. 6. (1) Any application subject to comparative review under Section 22229 of the Code, being  
 277 Section 333.22229 of the Michigan Compiled Laws, or UNDER these standards shall be grouped and  
 278 reviewed COMPARATIVELY with other applications in accordance with the CON rules, applicable to  
 279 comparative reviews.

280  
 281 (2)(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform  
 282 Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the  
 283 Michigan Compiled Laws. The number of points awarded shall be calculated by dividing the number of  
 284 deaths reported to the OPO by the total number of eligible deaths reported to the Department and  
 285 multiplying the product by 4. The maximum number of points that can be awarded under this subsection  
 286 is 4. An applicant shall provide, in the application at the time it is submitted to the Department,  
 287 documentation of the total number of eligible deaths at the licensed site at which the proposed  
 288 transplantation service will be provided, for the most recent year for which the Department has verifiable  
 289 data.

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

| 294 | 295 Number of            |             |
|-----|--------------------------|-------------|
| 296 | 296 Transplant Programs  | 296 Points  |
| 297 | 297 in HSA               | 297 Awarded |
| 298 | 299 Two or more programs | 0           |
| 300 | 300 One program          | 2           |
| 301 | 301 No programs          | 4           |

302  
 303 (c) A qualifying project will have up to 4 points awarded based on the percentage of the  
 304 medical/surgical indigent volume at the licensed hospital site at which the proposed heart/lung or liver  
 305 transplantation service will be provided in accordance with the following:

306 (i) For each applicant in the same comparative group, determine the medical/surgical indigent  
 307 volume, rounded to the nearest whole number, for each licensed hospital site at which a heart/lung or  
 308 liver transplantation service is proposed to be provided. Determine the licensed hospital site that has the  
 309 highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for  
 310 that licensed hospital site by 4.0. The result is the indigent volume factor.

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

314 For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its  
 315 total charges expressed as a percentage as determined by the Michigan Department of Community  
 316 Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Hospital  
 317 Program Manual. The indigent volume data being used for rates in effect at the time the application is  
 318 deemed submitted will be used by the Department in determining the number of points awarded to each

319 qualifying project.

320 (d) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-  
321 month period prior to the date an application is submitted to the Department, at least 15 patients received  
322 pre- and post-transplant care at the licensed hospital-site at which the heart/lung or liver transplant  
323 procedures will be performed and were referred for and received a heart/lung or liver transplant at an  
324 existing heart/lung or liver transplantation service, and submits documentation from the existing  
325 heart/lung or liver transplantation service(s) of these referrals.  
326

327 (3) Each application in a comparative review group shall be individually reviewed to determine  
328 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section  
329 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the  
330 Code and these standards. If the Department determines that one or more of the competing applications  
331 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The  
332 Department shall approve those qualifying projects which, taken together, do not exceed the need, as  
333 defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have  
334 the highest number of points when the results of subsection (2) are totaled. If two or more qualifying  
335 projects are determined to have an identical number of points, the Department shall approve those  
336 qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the  
337 Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications  
338 were received by the Department, based on the date and time stamp placed on the application for BY  
339 THE CON form (form T-150-G-1.01 or any subsequent replacement form) by the Division of Health  
340 Facility Development (or the administrative unit of the Department responsible for administering the CON  
341 program) when an application is submitted.  
342

343 (4) THE MINIMUM NUMBER OF POINTS WILL BE AWARDED TO AN APPLICANT UNDER THE  
344 INDIVIDUAL SUBSECTIONS OF THIS SECTION FOR CONFLICTING INFORMATION PRESENTED IN  
345 THIS SECTION AND RELATED INFORMATION PROVIDED IN OTHER SECTIONS OF THE CON  
346 APPLICATION. No points will be awarded to an applicant under specific subsections of Section 6 if  
347 information presented in Section 6 is inconsistent with related information provided in other portions of the  
348 CON application.  
349

350 **Section 7. Project delivery requirements -- terms of approval for all applicants**  
351

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

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

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

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

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

361 (ii) The applicant shall comply with applicable OPTN and Medicare requirements.

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

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

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

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

## Attachment B

372 of the institution.

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

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

377 (ix) The applicant shall maintain an organized institutional transplant registry for recording ongoing  
378 information on its patients being evaluated for transplant and on its transplant recipients and shall  
379 participate in the statewide transplantation registry operated by the Transplant and Health Policy Center  
380 and other national and international registries applicable to the transplantation service.

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

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

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

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

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

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

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

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

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

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

409 (E) AN APPLICANT SHALL AGREE TO ESTABLISH AND MAINTAIN ALL OF THE FOLLOWING:

410 (I) A WRITTEN AGREEMENT WITH THE FEDERALLY APPROVED OPO WHOSE DESIGNATED  
411 SERVICE AREA INCLUDES THE LOCATION OF THE PROPOSED TRANSPLANTATION SERVICE;

412 (II) ORGAN PRESERVATION CAPABILITY;

413 (III) AN ORGANIZED 24-HOUR TRANSPORT SYSTEM FOR TRANSPORTATION OF ORGANS,  
414 DONORS, AND BLOOD SERUM;

415 (IV) AN ORGANIZED 24-HOUR COMMUNICATION SERVICE CAPABLE OF SERVING THE  
416 TRANSPLANT TEAM AND OTHERS, AS APPROPRIATE;

417 (V) A CYCLOSPORINE ASSAY LABORATORY WITH RESULTS AVAILABLE ON THE SAME DAY;

418 (VI) AN IMMUNOLOGIC MONITORING LABORATORY;

419 (VII) A SPECIALIZED INPATIENT TRANSPLANTATION UNIT;

420 (VIII) NURSES WITH SPECIALIZED TRAINING ASSIGNED TO OPERATING ROOM(S) AND  
421 INTENSIVE CARE UNIT(S) USED IN CONJUNCTION WITH THE TRANSPLANTATION SERVICE,  
422 TRAINED IN THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT AND MANAGING  
423 IMMUNO-SUPPRESSED PATIENTS.

424 (A) A MEDICAL STAFF AND GOVERNING BOARD POLICY THAT PROVIDES FOR THE

SELECTION OF CANDIDATES FOR ORGAN TRANSPLANTATION PROCEDURES IN ACCORDANCE WITH THE PATIENT SELECTION CRITERIA APPROVED BY THE DEPARTMENT;

(B) AN ETHICS COMMITTEE OR HUMAN USE COMMITTEE TO REVIEW AND APPROVE THE INSTITUTION'S PROTOCOLS RELATED TO ORGAN TRANSPLANTATION, INCLUDING PROTOCOLS INVOLVING THE SELECTION OF DONORS AND RECIPIENTS; AND

(IX) A MULTI-DISCIPLINARY TRANSPLANT RECIPIENT EVALUATION COMMITTEE.

(F) AN APPLICANT SHALL AGREE THAT THE TRANSPLANTATION SERVICE SHALL BE STAFFED WITH QUALIFIED ADULT AND PEDIATRIC, AS APPLICABLE, TRANSPLANT SURGEON(S) AND TRANSPLANT PHYSICIAN(S). FOR PURPOSES OF EVALUATING THIS SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE TRAINING OF THE SURGEON(S) AND PHYSICIAN(S) IF THEY MEET THE REQUIREMENTS FOR CERTIFICATION BY MEDICARE OR THE OPTN. HOWEVER, THE APPLICANT MAY SUBMIT AND THE DEPARTMENT MAY ACCEPT OTHER EVIDENCE THAT THE SURGEON(S) AND PHYSICIAN(S) ARE QUALIFIED.

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

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

~~Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:~~

~~(a) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed transplantation service;~~

~~(b) organ preservation capability;~~

~~(c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;~~

~~(d) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;~~

~~(e) a cyclosporine assay laboratory with results available on the same day;~~

~~(f) an immunologic monitoring laboratory;~~

~~(g) a specialized inpatient transplantation unit;~~

~~(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient and managing immuno-suppressed patients.~~

~~(i) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;~~

~~(j) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients; and~~

~~(k) a multi-disciplinary transplant recipient evaluation committee.~~

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

**Section 98. Additional PROJECT DELIVERY REQUIREMENT Terms of approval -FOR- applicants proposing heart or heart/lung or lung transplantation services**

**Sec. 98. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be staffed and provided by at least the following:**

(a) cardiologists or surgeons trained in endocardial biopsy;

- 478 (b) cardiologists and surgeons trained in immunosuppression techniques;
- 479 (c) both adult and pediatric, as appropriate, cardiologists and surgeons;
- 480 (d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants  
481 in animals in a setting simulating the human situation;
- 482 (e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with  
483 one surgical team continuously available for organ retrieval thereby enabling a second team to  
484 simultaneously begin performing a recipient operation;
- 485 (f) a pathologist capable of diagnosing rejection on endocardial biopsies; and
- 486 (g) an anesthesiologist trained in open heart surgery.
- 487 (2) An applicant must demonstrate heart transplant patient survival rates at one year and two years  
488 after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must  
489 demonstrate patient survival rates at one and two years after transplantation of no less than the national  
490 average survival rate for the specific transplant type for the most recent year for which data is published  
491 by the OPTN.

492  
493 **Section 409. Additional PROJECT DELIVERY REQUIREMENTS FOR ~~terms of approval --~~**  
494 **~~applicants proposing~~ liver transplantation services**  
495

496 **Sec. 409. (1) An applicant shall agree that the liver transplantation service will be staffed and**  
497 **provided** by at least the following:

- 498 (a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals  
499 in a setting simulating the human situation;
- 500 (b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy,  
501 repair of biliary strictures, and Porto systemic shunts;
- 502 (c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical  
503 staff;
- 504 (d) a pathologist capable of diagnosing hepatic rejection;
- 505 (e) anesthesiologist(s) trained in liver transplantation;
- 506 (f) two liver transplant surgical teams, with one surgical team continuously available for organ  
507 retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in  
508 preparation for liver implantation; and
- 509 (g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available  
510 for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement  
511 which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver  
512 transplant recipient operation; and, a veno-venous bypass system which does not require heparin.
- 513
- 514 (2) The applicant shall establish and maintain all of the following:
  - 515 (a) nuclear HID biliary scan availability;
  - 516 (b) a continuously available coagulation laboratory; and
  - 517 (c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of  
518 plasma on demand.
- 519
- 520 (3) An applicant must demonstrate patient survival rates at one year and two years after  
521 transplantation of no less than the national average survival rate for the most recent year for which data is  
522 published by the OPTN.
- 523

524 **Section 4110. Documentation of projections**  
525

526 **Sec. 4110.** An applicant required to project volumes of service under sections 4 or 5 shall specify how  
527 the volume projections were developed. This specification of projections shall include a description of the  
528 data source(s) used, assessments of the accuracy of these data and the statistical method used to make  
529 the projections. Based on this documentation, the Department shall determine if the projections are  
530 reasonable.

531 | **Section 4211. Health Service Areas**

532

533 | **Sec. 4211. Counties assigned to each of the health service areas are as follows:**

534

535 | HSACOUNTIES

536

|         |            |         |           |
|---------|------------|---------|-----------|
| 537   1 | Livingston | Monroe  | St. Clair |
| 538     | Macomb     | Oakland | Washtenaw |
| 539     | Wayne      |         |           |

540

|         |         |           |         |
|---------|---------|-----------|---------|
| 541   2 | Clinton | Hillsdale | Jackson |
| 542     | Eaton   | Ingham    | Lenawee |

543

|         |         |           |            |
|---------|---------|-----------|------------|
| 544   3 | Barry   | Calhoun   | St. Joseph |
| 545     | Berrien | Cass      | Van Buren  |
| 546     | Branch  | Kalamazoo |            |

547

|         |         |          |         |
|---------|---------|----------|---------|
| 548   4 | Allegan | Mason    | Newaygo |
| 549     | Ionia   | Mecosta  | Oceana  |
| 550     | Kent    | Montcalm | Osceola |
| 551     | Lake    | Muskegon | Ottawa  |

552

|         |         |        |            |
|---------|---------|--------|------------|
| 553   5 | Genesee | Lapeer | Shiawassee |
|---------|---------|--------|------------|

554

|         |         |          |           |
|---------|---------|----------|-----------|
| 555   6 | Arenac  | Huron    | Roscommon |
| 556     | Bay     | Iosco    | Saginaw   |
| 557     | Clare   | Isabella | Sanilac   |
| 558     | Gladwin | Midland  | Tuscola   |
| 559     | Gratiot | Ogemaw   |           |

560

|         |            |             |              |
|---------|------------|-------------|--------------|
| 561   7 | Alcona     | Crawford    | Missaukee    |
| 562     | Alpena     | Emmet       | Montmorency  |
| 563     | Antrim     | Gd Traverse | Oscoda       |
| 564     | Benzie     | Kalkaska    | Otsego       |
| 565     | Charlevoix | Leelanau    | Presque Isle |
| 566     | Cheboygan  | Manistee    | Wexford      |

567

|         |           |          |             |
|---------|-----------|----------|-------------|
| 568   8 | Alger     | Gogebic  | Mackinac    |
| 569     | Baraga    | Houghton | Marquette   |
| 570     | Chippewa  | Iron     | Menominee   |
| 571     | Delta     | Keweenaw | Ontonagon   |
| 572     | Dickinson | Luce     | Schoolcraft |

573

574 | **Section 4312. Effect on prior CON Review Standards; comparative reviews**

575

576 | **Sec. 4312. (1)** These CON review standards supersede and replace the CON Review Standards for  
 577 | Extrarenal Transplantation FOR HEART/LUNG AND LIVER TRANSPLANTATION Services approved by  
 578 | the CON Commission on June 4, 1997~~MARCH 9, 2004~~ and effective on July 26, 1997~~JUNE 4, 2004~~.

579

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