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.
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
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.
Access to Heart Transplant Services

All Organ Transplant Centers Located in Southeast Michigan
Population

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

2.8 Million

7.1 Million

County Boundary

Population 2000
Source: Claritas, Inc.
Population Growth in Western Michigan

Western Michigan growing more than twice as fast as East Michigan

+ 4.0%

+ 1.5%

Fastest Growing Counties (growth of 9% or more)

County Boundary

Source: Claritas, Inc.
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

Source: Spectrum Health Data Warehouse, Dec. 8, 2008
Heart Failure and Transplant Clinic

VAD Patients

Following 11 Patients

Transplant Patients

Following approximately 50 transplant Patients
Spectrum Health Referrals for Heart Transplant

- In State
- Out of State

Year:
- 2004
- 2005
- 2006
- 2007
- 2008

Values:
- 0
- 5
- 10
- 15
- 20
Proximity to Transplant Center Increases Access

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

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<th>Procedure</th>
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<th>O/E</th>
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</table>

Deaths in hospital or within 30 days of operation
# Health Grades 2009 – Coronary Bypass Surgery

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<th>Hospital’s Name</th>
<th>In hospital Mortality (Survival)</th>
<th>In hospital +1 Month (Recovery +30)</th>
<th>In hospital +6 Months (Recovery +180)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectrum Health</td>
<td>*****</td>
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</tr>
<tr>
<td>Henry Ford Hospital</td>
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<td>***</td>
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</tr>
<tr>
<td>University of Michigan</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
</tbody>
</table>

- **Best ******
- **As Expected *****
- **Poor ***
# Health Grades 2009 – Valve Surgery

<table>
<thead>
<tr>
<th>Hospital’s Name</th>
<th>InHospital Mortality (Survival)</th>
<th>Inhospital +1 Month (Recovery +30)</th>
<th>Inhospital +6 Months (Recovery +180)</th>
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<td>***</td>
</tr>
</tbody>
</table>

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**

- Spectrum Health - Grand Rapids: 61,793
- Borgess Medical Center: 60,735
- Munson Medical Center: 65,024
- Mercy General Health Partners - Mercy Campus: 71,361
- Bronson Methodist Hospital: 82,601

**CABG Charges - Eastern Michigan Hospitals**

- University of Michigan Health System: 92,575
- Oakwood Hosp & Med Center - Dearborn: 83,718
- Beaumont Hospitals - Royal Oak: 100,981
- St. John Hospital and Medical Center: 102,713

Source: MedPar 2007
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
- Renucci 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

- Jackson Memorial
- Tampa General
- St. Luke's/Mayo Clinic
- Shands Hospital
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!
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR HEART/LUNG AND LIVER TRANSPLANTATION SERVICES


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. PERSUANT 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 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 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
perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

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

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

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

(iJ) "OPO" or "Organ Procurement Organization" OR "OPO" means an organ procurement organization as defined by Title 42, Part 485.302. "ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK" OR "OPTN" means the organization contracted by the federal Department of Health and Human Services to operate the organ procurement and transplantation network. "ORGAN PROCUREMENT ORGANIZATION" OR "OPO" MEANS AN ORGAN PROCUREMENT ORGANIZATION AS DEFINED BY TITLE 42, PART 485.302.

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

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

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

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

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

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

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

Section 3. Requirements for approval— all applicants

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

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

(2) An applicant must provide, at the time the CON application is submitted, an implementation plan for the proposed transplantation service. 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 PERFORM A TRANSPLANT PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT CHANGES HAVE OR WILL BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE INITIATED AND PROVIDED ON A REGULAR BASIS.
3. An application which proposes a joint sharing arrangement for a transplantation service which involves more than one licensed site shall demonstrate all of the following:

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

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

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

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

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

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

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

and

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

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

Section 4. Additional requirements for applicants seeking approval to provide heart or heart/lung or lung transplantation services

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

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

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

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

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

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

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

(d) continuously available coagulation laboratory services; and

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

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

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

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

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

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

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

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

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

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

Section 5. Additional requirements for applicants seeking approval to provide liver
transplantation services

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

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

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

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

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

(b) an intensive care unit with 24-hour per day on-site physician coverage;
(c) endoscopic retrograde cholangiopancreatography (ERCP) availability;
(d) percutaneous cholangiogram availability;
(e) percutaneous liver biopsy capability;
(f) a rapid blood infusion system;
(g) hemoperfusion; and
(h) a rapid red blood cell (RBC) blood saver system.

Section 6. REVIEW STANDARDS FOR Additional requirements for applications included in comparative reviews

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

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

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

<table>
<thead>
<tr>
<th>Number of Transplant Programs in HSA</th>
<th>Points Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two or more programs</td>
<td>0</td>
</tr>
<tr>
<td>One program</td>
<td>2</td>
</tr>
<tr>
<td>No programs</td>
<td>4</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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

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

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

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

(b) Compliance with applicable safety and operating standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(II) ORGAN PRESERVATION CAPABILITY;

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

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

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

(VI) AN IMMUNOLOGIC MONITORING LABORATORY;

(VII) A SPECIALIZED INPATIENT TRANSPLANTATION UNIT;

(VIII) 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;

(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 REQUIREMENTSTerms of approval—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;

CON Review Standards for Heart/Lung and Liver Transplantation Services
Draft Technical Changes for Heart/Lung and Liver Transplantation Standard Advisory Committee
Meeting on 7/16/09
(b) cardiologists and surgeons trained in immunosuppression techniques;
(c) both adult and pediatric, as appropriate, cardiologists and surgeons;
(d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants in animals in a setting simulating the human situation;
(e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing a recipient operation;
(f) a pathologist capable of diagnosing rejection on endocardial biopsies; and
(g) an anesthesiologist trained in open heart surgery.

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

Section 409. Additional PROJECT DELIVERY REQUIREMENTS FOR applicants proposing liver transplantation services

Sec. 409. (1) An applicant shall agree that the liver transplantation service will be staffed and provided by at least the following:
(a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals in a setting simulating the human situation;
(b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy, repair of biliary strictures, and Porto systemic shunts;
(c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical staff;
(d) a pathologist capable of diagnosing hepatic rejection;
(e) anesthesiologist(s) trained in liver transplantation;
(f) two liver transplant surgical teams, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in preparation for liver implantation; and
(g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver transplant recipient operation; and, a veno-venous bypass system which does not require heparin.

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

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

Section 4110. Documentation of projections

Sec. 4110. An applicant required to project volumes of service under sections 4 or 5 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.
Section 4211. Health Service Areas

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

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

Section 1312. Effect on prior CON Review Standards; comparative reviews

Sec. 1312. (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 and effective on July 26, 1997.

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