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

Thursday, June 25, 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:

James F. Ball, Chairperson, Michigan Manufacturers
Wayne Cass, Vice-Chairperson, Coalition of Labor Organizations Michigan State
Heidi Gustine, Munson Medical Center (Arrived at 9:11 a.m.)
Robert L. Hooker, MD, West Michigan Cardiothoracic Surgeons, PLC
Jerry Johnson, MD, Blue Cross Blue Shield of Michigan
Alan Koffron, MD, Beaumont Hospitals
Marwan S. Abdoulijoud, MD, Henry Ford Hospital
Richard E. Pietroski, Gift of Life Michigan
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
Jeannette Prochazka, Borgess Health

C. Michigan Department of Community Health Staff Present:

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

II. Declaration of Conflicts of Interests

No conflicts were noted for the record.

III. Review of Agenda

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

IV. Review of Minutes of May 19, 2009

Motion by Dr. Abdoulijoud, seconded by Mr. Pietroski, to accept the minutes as presented.
Motion Carried.

V. BCBSM Data for Transplants Performed in Out of State Centers for Their Subscribers Presentation

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

Discussion followed.

VI. Organ Export Distribution Data Presentation

Mr. Pietroski provided an oral and written presentation (Attachment B).

Discussion followed.

VII. CMS and UNOS Requirements for Heart/Lung & Liver Presentation Marianne Beach, Transplant Administrator for Henry Ford Health System

Marianne Beach, Transplant Administrator for Henry Ford Health System, provided an oral and written presentation (Attachment C).

Discussion followed.

Public Comment:
Barbara Jackson, Blue Cross Blue Shield of Michigan

VIII. Costs of Programs and Payer Requirements – Anne Murphy, Transplant Administrator, University of Michigan Health System

Anne Murphy, Transplant Administrator, University of Michigan Health System, provided an oral and written presentation (Attachment D).

Discussion followed.

Break from 11:09 a.m. to 11:23 a.m.

IX. Charge 1 Discussion

Motion by Vice-Chairperson Cass, seconded by Dr. Punch, to recommend continued regulations of Heart/Lung & Liver Transplantation Services.
Motion Carried.

X. Next Steps

Dr. Hooker offered to provide a presentation on West Michigan Access and Cost.

DCH Staff will provide summary of the Public Hearing testimony that was presented to the Commission. The SAC members will discuss the potentially outdated language from the public hearing testimony for sections 4, 8, 9, and 10 of the standards. Additionally, the department will present the technical language changes for the standards.

XI. Future Meeting Dates

July 16, 2009
August 13, 2009
September 15, 2009
October 15, 2009

XII. Public Comment

Bob Meeker, Spectrum Health

XIII. Adjournment

Motion by Mr. Pietroski, seconded by Dr. Johnson, to adjourn the meeting at 11:49 a.m. Motion Carried.

Attachment A

Blue Cross Blue Shield of Mi Solid Organ Transplants: Out of State Procedures: 2004-2008

Jerry A. Johnson, M.D.
Senior Medical Director
BCBSM
Medical Affairs

June 25, 2009

BCBSM Human Organ Transplant Program

- All BCBSM underwritten contracts that provide transplant coverage require the transplant to be performed in a “network facility”.
- Self funded groups may opt in, opt out or customize a network.
- The BCBSM transplant network is the Blue Distinction Centers for Transplants (BDCT).

BCBSM Human Transplant Program

- The BDCT Network is administered through the national Blue Cross Blue Shield Association in Chicago.
- BDCT offers established quality and credentialing standards along with contracted rates.
- Groups are able to experience cost savings and at the same time ensure high quality of care.

BCBSM Human Organ Transplant Program

- Our goal is to make sure each transplant performed is offered in a BDCT facility.
- For subscribers living in Michigan, our goal is that they will receive their transplant at a BDCT approved facility in Michigan.
- The vast majority of solid transplants provided to Michigan residents occur in approved facilities within the State of Michigan.

Attachment A

Total Solid Transplants performed in Mi and Total BCBSM Solid Transplants

	Total Solid Organ Transplants in Michigan	total BCBSM solid organ transplants
2004	288	102
2005	289	101
2006	288	109
2007	268	97
2008	data not available	105
average	283	103

Attachment A

Total BCBSM solid transplants performed: in state vs out of state

	Total BCBSM solid organ transplants	in state transplants		out state transplants	
		#	%	#	%
2004	102	83	81%	19	19%
2005	101	80	79%	21	21%
2006	109	92	84%	17	16%
2007	97	80	82%	17	18%
2008	105	89	85%	16	15%

Attachment A

Number of BCBSM solid transplants performed out of state, by region

Number of BCBSM member out state transplants by region

	East	West	UP
2004	15	1	3
2005	10	10	1
2006	5	6	6
2007	9	8	0
2008	7	9	0

Out of State Transplant Drivers:

1. Patient preference
2. Transplant type not available in Michigan
3. No BDCT approved facility in Michigan
4. Customer driven benefit design
5. Non accepted by in state programs
6. Significant family support system issues
7. Logistics/Proximity issues: acuity, organ viability, nearest BDCT facility

BCBSM Human Transplant Program: Conclusions

- The percentage of BCBSM transplants performed within Michigan has been pretty stable at between 80-85% since 2004.
- In general, no one region of the state appears to be disproportionately represented in cases going out of state.
- Multiple factors may contribute to cases going out of state, but most are driven by patient preference as allowed by benefit design.

Organ Export Distribution Data

HLLSAC Presentation
June 25, 2009

Richard Pietroski, Executive Director
Gift of Life Michigan

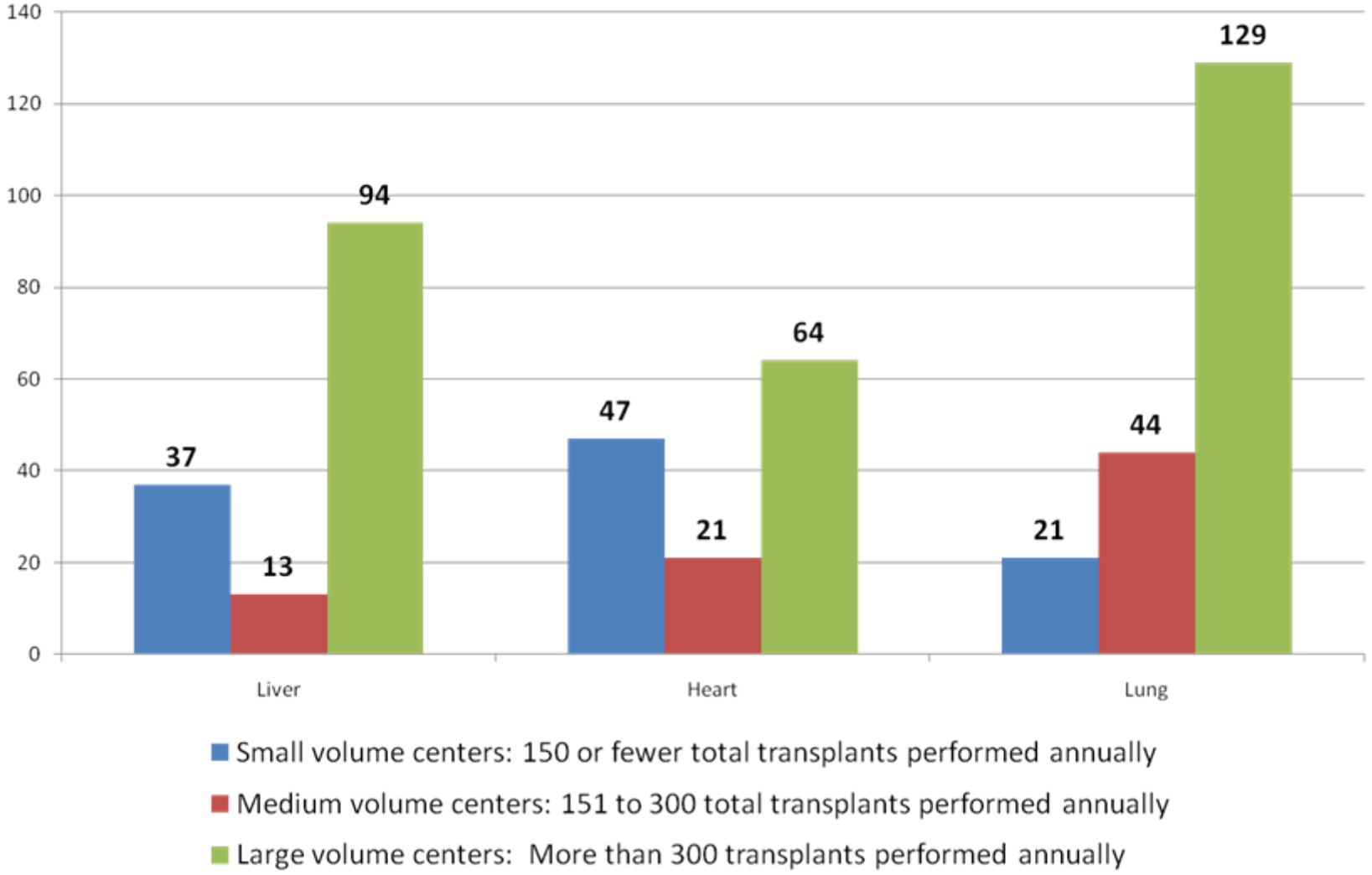
Attachment B

Overview of Specific Organ Exports 2006-2008

	ORGANS RECOVERED	LOCALLY TXP'D	EXPORTED
Liver	720	562	126
Heart	254	155	140
Lung	392	281	137
Total	**1366**	**998**	**403**

Attachment B

Number of Organs Exported Relative to Number of Total Transplants Performed by Center Aggregate Totals: 2006-2008



Source for center volume: www.optn.org, as of June 12, 2009

DISPOSITION OF LIVERS EXPORTED TO CANADA BY YEAR

Between 2006-2008, one liver was exported (2006) to a patient who was 3 years old, ABO=B. The center was located in Ontario.

DISPOSITION OF HEARTS EXPORTED TO CANADA BY YEAR

	2006	2007	2008	Totals
Ontario		2	2	4
Quebec	1	1		2
Alberta		1		1

Export Reasons
Hearts Exported to Canada 2006-2008

	2006	2007	2008
Pediatric	1	3	
ABO=B			1
Donor Quality			
Cocaine History		1	
Expedited Placement			1

DISPOSITION OF LUNGS EXPORTED TO CANADA BY YEAR

	2006	2007	2008	Totals
Ontario	14	6	8	28
Alberta		2		2

Export Reasons
Lungs Exported to Canada 2006-2008

	2006	2007	2008	Totals
Age > 60 yrs	2	2	2	6
Age > 50 < 60	2		2	4
ABO = B	4	2	4	10
ABO = AB		2		2
Donor Quality				
Chest tubes		2		2
Sputum Culture	2			2
Smoking History	2			2
Drug/Jail History	2			2

Rich Pietroski
Gift of Life Michigan

800-482-4881
rpietroski@giftoflifemichigan.org

Attachment C

CMS and UNOS Regulatory Requirement for Abdominal Transplantation

Marianne Beach-Langlois
Transplant Administrator
Henry Ford Hospital

Attachment C

New Medicare Approval Requirement

- All hospital transplant programs, approved for Medicare participation as of June 28, 2007
- Approved either under the ESRD Conditions for Coverage or the National Coverage Decisions)
- Must submit a request for new approval under the Conditions of Participation established by the new regulation.
- Request must be submitted to CMS **by December 26, 2007** (180 days from the effective date of the regulation.)

Requests may be mailed to:

Centers for Medicare and Medicaid Services
Attention: Sherry Clark
Mail Stop: S2-12-25
7500 Security Blvd.
Baltimore, MD 21244

Or faxed to: (410) 786-0194 Attention: Sherry Clark

Henry Ford Health System

Attachment C

§ 482.72 Condition of participation: OPTN Membership

A transplant center must be located in a transplant hospital that is a member of and abides by approved rules and requirements of the OPTN established and operated in accordance with §372 of the Public Health Service (PHS) Act (42 U.S.C. section 274).

Attachment 2

Required Information on All Applications for Medicare Approval

- Name of Transplant Hospital
- Address of Transplant Hospital
- Address of Transplant Program (if different from transplant hospital)
- Name of the Hospital Representative (for each program approval requested)
- Telephone Number of Hospital Representative (for each program approval requested)
- E-Mail Address of the Hospital Representative (for each program approval requested)
- Fax Number of the Hospital Representative (for each program approval requested)
- National Provider Identifier (NPI) Number for the Hospital
- National Provider Identifier Number (NPI) (for each program approval requested- if different from the participating hospital NPI)
- CMS Certification Number (Previously the Medicare Provider Number)
- Organ Procurement Transplant Network (OPTN) Membership Code (four letter code)
- Type(s) of Transplant Program(s) For Which Medicare Approval is Requested.
- Name of Primary Transplant Surgeon (first & last) (for each program approval requested)
- Name of Primary Transplant Physician (first and last) (for each program requested)
- Date Program Initially Medicare Approved (kidney programs only)

If you are requesting approval for a pediatric heart transplant program under the alternative approval criteria (42CFR 482.76(d)) please include the following with your application:

- The National Provider Identifier (NPI) of the Jointly Operating Facility
- Name of the Shared Transplant Surgeon

Note: All requests for Medicare approval must be signed and dated by an authorized representative of the hospital.

Attachment C

§482.74 Condition of Participation: Notification to CMS

A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that would alter elements in the approval/reapproval application:

- A change in key staff members of the transplant team
- A decrease in the center's volume or survival rates
- Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs
- Inactivation of the transplant center

Attachment C

UNOS Bylaws Requirements

- UNOS application must be completed and submitted to become a UNOS approved transplant center that may accept organ offers.
- Transplant Programs
  - Must identify UNOS qualified surgeon and physician available 365 days, 24/7 coverage.
  - Surgeon/physician must be available on hospital premises within one hour ground transportation for urgent patient issues.
  - Cannot be director of another tx center program unless there is sufficient coverage at current center.

Attachment C

UNOS Bylaws Requirements

- Surgeon and Medical Director Experience Required

Kidney Surgical	Board of Surgery/Urology	30 txs, 15 procurements and mgmt of pts over 2 yrs.
Kidney Medical	Board of Nephrology	30 recipients first 3 mths, observe 3 procurements, 3 donors
Liver Surgical	Board of Surgery/Urology	45 txs, 20 procurements over 2 yrs.
Liver Medical	Board of Gastroenterology	1 yrs trng in care of 30 recipients first 3 mths, observe 3 procurements.
Heart Surgical	Board of Thoracic Surgery	20 txs. Involved in all aspects of patient care over 2 yrs.
Heart Medical	Board of Cardiology	Care of 20 recipients over 2 yrs. Observe 3 procurement and 3 txs
Lung Surgical	Board of Surgery/Urology	15 txs, 10 procurements and all aspects of pt. care
Lung Medical	Board of Internal Medicine	Care of 15 recipients, observe 3 txs and 3 procurements.

Henry Ford Health System

Attachment C

UNOS Bylaws Requirements

- Survival Rates – if low survival rate, subject to evaluation by MPSC and potential site visit at your cost.
- Facilities – must allocate sufficient OR, intensive care and surgical beds and personnel.
- Recipient Selection – must have procedures to assure organs are distributed in a fair and equitable manner.
- Patient Notification – Notify pts in 10 days of listing decision, removal and document in pt. EMR.
- Collaborative Support – must have experts in the field to support patients.
- Ancillary Services – immediate access to sophisticated microbiology, clinical chemistry, tissue typing, radiology, and monitoring of immunosuppressive drugs.
- Blood Bank Support – Access to large quantities of blood.

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Attachment C

Condition: Data submission, clinical experience, and outcome requirements

Standard:	**Data Submission**
CMS 482.80	95% required data within 90 days of due date
UNOS	Same
Compliance Strategy	Report available on UNET: Tiedi/Reports/Compliance Report OPTN provides info to CMS

Attachment C

Condition: Data Submission, Clinical Experience, and Outcome Requirements

Standard	Clinical Experience
CMS Annual Volume	•Heart, liver, lung, intestine = 10 transplants average over 3 yr period •Kidney = 3 transplants initial approval •No annual volume for heart/lung, pancreas and pediatric programs
UNOS	NA
Source/ Strategy	Internal monitoring

Attachment C

Transplant Center of Excellence (COE)

Volume Requirements for Payor Participation

Organ/BMT	Blue Distinction for Transplant (BDCT)	CIGNA LifeSource	INTERLINK	Optum Health (United Resource Network)
Heart	20 in two years, min 8 per year	12 per year	12 per year and 250 open heart	20 per year
Lung	20 in two years, min 8 per year	12 per year	15 per year	20 per year
Liver	60 Deceased or LD over 2 years, no fewer than 25 in one year. LD perform 12 over 4 years.	12 per year	30 per year	35 per year

Attachment C

Condition: Data Submission, Clinical Experience, and Outcome Requirements

Standard	Outcome Measures
CMS	•Except for lung, ped & adult reviewed separately •No outcome criteria for heart/lung, intestine & pancreas •Expected 1 year pt and graft survival not statistically lower measured as: O-E >3 O/E>1.5 1-sided p <0.05
UNOS	Programmatic reviews occur when survival lower then calculated expected (written site survey, on-going monitoring, peer review, MPSC oversight)
Source/ Strategy	SRTR Center Specific Reports - www.ustransplant.org

Condition: Patient and Living Donor Selection

Standard	Patient Selection Criteria
CMS 482.90	•Must assure fair & non-discriminatory alloc of organs •include psychosocial eval •ABO x 2 documented •documentation that criteria used for each pt.
UNOS	ABO x 2 required at listing
Source/ Strategy	•Policies required: –Patient Selection –ABO Verification –Listing Policy –Documentation Policy

Condition: Patient and Living Donor Selection

Standard	Living Donor Selection Criteria
CMS	•Ensure medical and psychosocial eval for living donor •Document suitability for donation in record •Document informed consent given to living donor
UNOS	NA
Source/ Strategy	•Policy Development –Live Donor Selection and Evaluation –Live Donor Consent Process –Documentation Process

Attachment C

Condition: Organ Recovery and Receipt

Standard	**Organ Recovery and Receipt**
CMS 482.92	•ABO verification by team prior to recovery •Transplant surgeon and 1 other licensed professional must verify ABO at receipt/transplantation
UNOS	Same documentation required
Source/ Strategy	•Policy Development: –Operation Room Policy for deceased and living donor recovery and transplantation. –ABO verification Policy

Attachment C

Condition: Patient and Living Donor Management

Standard	**Patient and Living Donor Care**
CMS 482.94	Each patient and/or LD is under care of a multi-disciplinary team coordinated by a physician throughout transplantation and donation.
UNOS	NA
Source/ Strategy	• Policy Development – Waitlist Management Policy – Discharge Policy – Live Donor Post Operative Management Policy – Care Plans for the live donor and/or Recipient – Standardized Discharge Instructions – Education Booklets or Videos – Multidisciplinary Team Policy

Attachment C

Condition: Patient and Living Donor Management

Standard	Waitlist Management
CMS	•Update patients' clinical information on an on-going basis •Remove patients from the center's waitlist if dies or transplanted •Notify UNOS w/in 24 hours of removal
UNOS	Removal w/in 24 hours for death or transplant
Source/ Strategy	•Policy Development –Waitlist Management Policy –Updating Unet Policy –OPTN/UNOS audit Policy –Patient Evaluation Policy

Attachment C

Condition: Patient and Living Donor Management

Standard	Patient Records
CMS	•Maintain up-to-date records for each patient evaluated •Include notification to patient (& dialysis facility) of decision to list or not list. •Removal from waitlist (for other then death/transplant) •Documentation of multidisciplinary care planning pre and at discharge.
UNOS	•Letters for listing, decision not to list and removal required to be sent w/in 10 days of action. •Letter dates must match actual waitlist and removal date.
Source/Strategy	•Notification Policy •Standard Form Letters •Documentation in patient record.

Attachment C

Condition: Patient and Living Donor Management

Standard	Social Services
CMS	TC must make available social services from a qualified SW to patients, living donors and family members.
UNOS	NA
Source/ Strategy	•Include SW on org chart •Document that SW represented at selection committee meetings •Include SW availability in Informed Consent documents •Transplant Social Work Policy •Job Description

Attachment C

Condition: Patient and Living Donor Management

Standard	**Nutritional Services**
CMS	TC must make available nutritional assessments and diet counseling services (by a qualified dietician) to patients and living donors.
UNOS	NA
Source/ Strategy	•Include dietician on org chart •Document that dietician represented at selection committee meetings •Include dietician availability in Informed Consent documents •Transplant Nutrition Assessment Policy •Job Description

Attachment C

Condition: Quality Assessment and Performance Improvement (QAPI)

Standard	Components of a QAPI Program
CMS 482.96	•TC must have a data-driven QAPI program to monitor & evaluate performance of all transplantation services. •Must take actions that result in PI and track performance to ensure sustained.
UNOS	NA
Source/ Strategy	•Keep transplant "dashboard" •Dedicate quarterly pt selection meeting to QAPI discussion and keep minutes in central binder •Form QAPI committee across programs and conduct special review projects with hospital quality. •Maintain list of all "PI" projects done throughout the year (effort to improve customer service, revision of patient selection criteria, etc.)

Attachment C

Condition: Quality Assessment and Performance Improvement (QAPI)

Standard	Adverse Events
CMS	•Written policies to address process for id, reporting, analysis and prevention of adverse events. •TC must use analysis to impact future practice so not repeated.
UNOS	NA
Source/ Strategy	•Review hospital-wide policy for adverse event reporting. •Morbidity and Mortality Conferences

Condition: Human Resources

Standard	**Director of a Transplant Center; Transplant Surgeon & Physician**
CMS 482.98	TC must be under general supervision of qualified transplant surgeon or physician TC must identify UNOS primary surgeon & physician.
UNOS	Primary surgeon and primary physician
Source/ Strategy	•Org chart with surg & med directors •Job Description •Copies of UNOS primary applications

Condition: Human Resources

Standard	Clinical Transplant Coordinator
CMS	TC have a qualified clinical transplant coordinator (RN) to ensure the continuity of care of pts and LD throughout transplantation and donation.
UNOS	Requires clinical transplant coordinator with defined responsibilities
Source/ Strategy	•Org chart with coordinator(s) •Ensure job description includes CMS & UNOS defined functions/requirements

Condition: Human Resources

Standard	Independent Living Donor Advocate or LD Advocate Team
CMS	•Must not be involved in transplantation activities on a routine basis •Knowledge of LD, transplantation, medical ethics, informed consent
UNOS	NA
Source/ Strategy	•Separate RN coordinator(s)/provider for donor evaluation •Letter to donors explaining DA availability •Documentation of discussions that DA has with donor •Documentation of attendance of DA at patient selection committee meetings when donors presented

Condition: Human Resources

Standard	Transplant Team
CMS	•Multidisciplinary Team must be composed of individuals from medicine, surgery, nursing, nutrition, social services, transplant coordination, pharmacology
UNOS	Also Required
Source/ Strategy	•Org chart •Minutes from weekly selection meetings •Sign-in sheet at rounds and/or selection meetings •Responsibilities of each member •Ability for each transplant employee to identify at least one person for each key role

Condition: Human Resources

Standard	Resource Commitment
CMS	TC must demonstrate availability of expertise in internal med, surgery, anesth, immunology, ID, pathology, radiology, and blood banking
UNOS	Also Required
Source/ Strategy	•Inventory of key contact people in each specialty area maintained

Condition: Organ Procurement

Required Condition – Written Agreement with OPO	
CMS	TC must demonstrate availability of expertise in internal med, surgery, anesth, immunology, ID, pathology, radiology, and blood banking
UNOS	Also Required
Source/ Strategy	•Contract signed by both Hospital/TC and OPO

Attachment C

Condition: Patient and Living Donor Rights

Standard	Informed Consent for Living Donors
CMS 482.102	•Must have written policy for the inf consent process •Informed consent must include fact that communication between donor & TC is confidential, eval process, procedure & post treatment, potential risks to donor, availability of alt treatments for recip, national & center outcomes, possibility of future health problems related to donation may not be covered by insurance/may impact ability to get insurance, right to opt out, non-Medicare center could effect recip ability to get immuno.
UNOS	NA
Source/ Strategy	•Agreement Form signed by patient in EMR •SRTR site for patient reference of survival data •Consent Policy

Attachment C

Condition: Patient and Living Donor Rights

Standard	Notification to Patients
CMS	•Must notify patients on wait list of information that could impact ability to get a transplant (for example only one surgeon on staff and what happens when out of town) •At least 30 days prior to Medicare approval terminated, must inform patients & assist transition to another TC.
UNOS	Similar
Source/ Strategy	•Written plan for what is done when coverage not available and how patients are informed. •Notification Policy

Attachment C

Condition: Additional Requirements for Kidney Transplant Centers

Standard	ESRD
CMS	•Kidney TCs must furnish services required for ESRD care including inpatient dialysis
UNOS	NA
Source/ Strategy	•Agreement with dialysis provider if not available at hospital

Attachment C

Condition: Additional Requirements for Kidney Transplant Centers

Standard	Participation with Network Activities
CMS	Kidney TCs must cooperate with ESRD Network
UNOS	NA
Source/ Strategy	•Maintain good standing with assigned Network

Web Site Resources

- CMS http://www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp#TopOfPage
- SRTR http://www.ustransplant.org
- UNET https://portal.unos.org/index.aspx

University of Michigan Health System

Transplant Commercial Insurance

and

Financial Investment for Transplant Program Start Up

June 25, 2009

Anne Murphy
annemurp@med.umich.edu

University of Michigan Health System

Transplant Centers of Excellence (COEs)

Attachment D

- **Primary Commercial Payers are Transplant Centers of Excellence (COEs)**
  - Also known as Transplant Networks
  - Represent Insurance Companies, HMOs, Self Funded Health Plans and Stop Loss Carriers
  - Provide Comprehensive Credentialing and Participation Criteria

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Transplant Centers of Excellence (COEs)

Attachment D

- Rigorous Standards for Transplant Program Acceptance into the Networks
  - Varied from Network to Network, and increasingly more stringent as time goes by
- Form relationships with Transplant Centers, offering consistent, high quality transplants
- Review these relationships annually to ensure continued qualification
- High Demand/Labor Intensive for Participating Programs – irrespective of program volume

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Transplant Centers of Excellence (COEs)

Attachment D

- **Most Commercial Transplants Are Paid Under these Centers Of Excellence:**
  - Aetna's Cofinity Network
  - Blue Distinction Centers for Transplant (Blue Cross)
  - Cigna Lifesource
  - Interlink
  - LifeTrac
  - OptumHealth (URN)
- **Very small percent of transplants outside of CMS and these Commercial Networks**

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Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Baseline of meeting CMS and UNOS standards
  - JCAHO Certification of the Facility/Hospital
  - Participation in an annual, exhaustive written survey process
  - Participation in initial on-site surveys and reviews, with periodic follow up visits (typically yearly)
  - Each Organ program (heart, liver, lung) assessed separately against different standards. Pediatric and Adult Programs assessed differently.

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Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Meet or exceed a standard set of guidelines – often considered proprietary and not available to the public
    - All have minimum experience requirements for surgeons and physicians
      - Typically current 2-3 year period for primary physician/Surgeon and 1 year for secondary
    - Pharmacist is dedicated to the transplant program and participates in patient management and education.
    - Dietician available to the program and participates in patient education
    - Program duration and number of transplants performed since inception – typically 2-3 years

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*Minimum Volume Requirements**

Attachment D

** Most recently available*

Organ	BDCT (Blue Cross)	CIGNA	Interlink	Optum Health
Heart	20 in two years Min 8 per year	12 per year	12 per year and 250 open heart	20 per year
Lung	20 in two years Min 8 per year	12 per year	15 per year	20 per year
Liver	60 Deceased or LD over 2 years No fewer than 25 in one year LD – at least 12 over 4 years	12 per year	30 per year	35 per year

University of Michigan Health System

Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Outcomes requirements for patient and graft (organ) survival
    - Meet or Exceed Statistically Expected Values
  - Threshold for number of transplants experiencing primary non-function
  - Waitlist Mortality Thresholds
  - Major complications Thresholds
  - Retransplant Rate Thresholds
  - Ventricular Assist Device (VAD) program or process/plan to allow patients access to these services – for Heart Programs
  - Has or makes referrals to qualified Rehabilitation Facilities

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Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - 24x7 availability of cardiothoracic surgery, bronchoscopy/endoscopy for Lung Programs
  - Favorable Case Rates – Cost Containment/Economies of Scale
  - Staff Training and Experience – NATCO Certification
  - Patient and Caregiver Education
  - Availability of Housing arrangements and transportation for Patients' Families
  - Availability of Organs in the Geographic Area of the Facility

University of Michigan Health System

Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Written Patient Eligibility Criteria
    - Process for re-evaluating on an annual basis
  - Written protocols
  - Clinical Trials
    - Accept AAMC principles for all clinical trials
  - Peer Reviewed Publishing

University of Michigan Health System

Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Committee Available to review ethical and medical considerations as needed
  - Regularly held, multi-disciplinary patient selection committee meetings
  - Process and Systems to review patient satisfaction

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Transplant Centers of Excellence (COEs)

Attachment D

- **What does it take to participate in one of these Networks?**
  - Transplant Specific Information Management System
  - Utilize a Histocompatibility Laboratory that meets UNOS requirements and is capable of performing histocompatibility testing, immunology, pathology, microbiology, virology and therapeutic drug monitoring
  - Infectious Disease Experience in the care of transplant patients and must have the skills and lab available to manage patient complications.
  - Access to support groups – including local and regional groups available pre and post transplant

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First Year Financial Investment For a Heart Transplant Program

Attachment D

- Staff and Benefits Cost for
  - 2 Cardiac Surgeons
  - 2 Cardiologists
  - Administrative Staff
  - Clinical Staff
- Transplant Specific Information System
- Other Operating Expenses

– Approximately $4.6M

University of Michigan Health System

Specific Questions Posed

Attachment D

- **Are there standards on Volume?**
  - Yes. CMS Baseline is "generally 10 transplants over a 12 month period", for heart, liver lung transplants.
  - Transplant Center of Excellence volume standards vary and can be significantly higher than CMS standards (e.g. BDCT/Blue Cross – no fewer than 25 livers per year)
- **Is there published data on the relationship between volume and quality?**
  - Yes, for both heart and liver transplants.
- **Are the same facilities, surgeons or teams used for all of the transplants in question?**
  - For heart and lung (thoracic) programs, generally the answer is yes, though some larger programs don't share resources.
  - Liver and kidney (abdominal) transplants are often done by the same surgeons or teams.
  - No cross over between abdominal and thoracic
  - Staff must be redundant so that you can meet the 24x7 demands of the program
- **Are there overlaps, economies and synergies of scale?**

  Yes, there are economies of scale in: administration, patient and staff education, regulatory compliance for UNOS/CMS/Commercial Payers, Contracting, Finance, Nurse Management, Quality Improvement, UNOS Data Reporting, Information Systems, Protocols, Policies and so on.

University of Michigan Health System

Specific Questions Posed

Attachment D

- **What is the process from a transplant recipient viewpoint?**
  - Patient Evaluation – rule out or listing on national waitlist
    - Some patients in the hospital, some out
  - When compatible organ is available, and patient has highest priority score, patient is called in for transplant
  - Donor team goes to the hospital to recover the organ
  - Once organ is viewed and deemed acceptable recipient operation commences
    - Thus the need for two surgeons – preferably three to allow for vacations and other absences
- **How long are transplant patients in the facility?**
  - Mean length of stay for Heart: 21 Days, Lung: 18 Days, Liver: 16 Days
- **To what extent are they separate from other patients?**
  - Not separate from all patients in all cases, but:
    - Must be away from infection – both inpatient and outpatient – Blue Cross Example
    - Must be on a unit where specialized education and care can take place
      - Training on post transplant medications
      - What to watch for post-transplant
      - Trough level blood draws

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Specific Questions Posed

Attachment D

- **When there is not a transplant going on what is the usage of the facilities or staff? Are they held open and available for transplant or used for general purposes?**
  - Resources are applied to the extent possible to other related activities that are not time sensitive
  - Must be ready and available to respond 24x7 to organ availability
- **Aren't there significant ongoing expenses?**
  - Yes. It's critical to maintain a core of specialty trained personnel on an ongoing, consistent basis, irrespective of transplant volume.