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

Thursday, August 13, 2009

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

APPROVED MINUTES

I. Call to Order

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

A. Members Present:

Marwan S. Abdoulijoud, MD, Henry Ford Hospital (Arrived at 9:31 a.m.)
James F. Ball, Chairperson, Michigan Manufacturers
Wayne Cass, Vice-Chairperson, Coalition of Labor Organizations Michigan State
Heidi Gustine, Munson Medical Center
Robert L. Hooker, MD, West Michigan Cardiothoracic Surgeons, PLC
Jerry Johnson, MD, Blue Cross Blue Shield of Michigan
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
Alan Koffron, MD, Beaumont Hospitals

C. Michigan Department of Community Health Staff Present:

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

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 July 16, 2009

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

V. Department Update

Ms. Rogers gave an update on the joint sharing language clarifying that there are only two heart and heart/lung programs.

Ms. Rogers reviewed the current CON Review Standards that have separate requirements for pediatrics and adults (Attachment A).

Discussion followed.

Motion by Dr. Punch, seconded by Dr. Hooker, to recommend that there will be no need to include separate pediatric requirements in the standards.
Motion Carried.

Break from 9:20 a.m. to 9:31 a.m.

VI. Proposed Liver Language Changes for Outdated Language

Dr. Abjoulijoud provided an oral and written presentation (Attachment B).

Discussion followed.

Motion by Dr. Abjoulijoud, seconded by Dr. Hooker, to approve proposed liver language changes (Attachment B) and adding compliance with OPTN and CMS requirements in Section 7 which is applicable to liver, heart, and heart/lung services, not Section 9 as proposed.
Motion Carried.

VII. Next Steps

Dr. Punch and Dr. Hooker will provide recommendations to update outdated language for heart and heart/lung at the next meeting.

Chairperson Ball gave a verbal and written presentation on his summary of the HLLSAC's current status. (Attachment C)

Discussion Followed.

Motion by Vice-Chairperson Cass, seconded by Dr. Punch, to areas accept elements 1 - 4 of Chairperson Ball's report (Attachment C).
Motion Carried.

Public Comment:

Bob Meeker, Spectrum Health

Motion by Vice-Chairperson Cass, seconded by Gustine, to accept element 5(1.) of Chairperson Ball's report (Attachment C).
Motion Carried.

Motion by Vice-Chairperson Cass, seconded by Ms. Gustine, to accept that no changes be made for the CAP, planning area, and comparative review criteria. Motion Carried.

VIII. Future Meeting Dates

September 15, 2009
October 15, 2009

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Johnson, seconded by Mr. Pietroski, to adjourn the meeting at 10:35 a.m.
Motion Carried

CERTIFICATE OF NEED (CON) REVIEW STANDARDS THAT CONTAIN SPECIAL PEDIATRIC REQUIREMENTS

Bone Marrow Transplantation Services

http://www.michigan.gov/documents/mdch/BMT_Standards_189310_7.pdf

Cardiac Catheterization Services

http://www.michigan.gov/documents/mdch/CC_Standards_204884_7.pdf

Computed Tomography (CT) Scanner Services

http://www.michigan.gov/documents/mdch/CON-212_CON_Rev_Stds_CT_Scanners_12-27-06_181839_7.pdf

Magnetic Resonance Imaging (MRI) Services

http://www.michigan.gov/documents/CON-213_CON_Rev_Stds_MRI_Svcs_10_156397_7.17.05.pdf

Open Heart Surgery Services

http://www.michigan.gov/documents/mdch/Open_Heart_Standards_204892_7.pdf

Positron Emission Tomography (PET) Scanner Services

http://www.michigan.gov/documents/mdch/PET_Standards_189312_7.pdf

Section 5: Language to Add (Consistency with Heart/Lung)

(5) An application which proposes a joint sharing arrangement for a liver 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 5(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 liver 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 liver transplantation procedures in the second 12-months of operation following the date on which the first liver transplant procedure is performed, and annually thereafter.

Section 9: Project Delivery Liver

REMOVE item 1(a)

DELETE item 2

ADD: Have an OPTN approved surgical and medical director with coverage that meets the 24/7, 365 days coverage requirements

Item 3: “An applicant must demonstrate patient and graft 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~~ within expected as determined by SRTR outcomes and published by the OPTN”

Remain a functionally active program by OPTN bylaws and Policies

Obtain and maintain CMS qualifications

Be in good standing with UNOS

Show collaborative support with experts in the field of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility and immunogenetics, and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support.

Immediate access to sophisticated microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as facilities required or capacity for monitoring immunosuppressive drugs

Blood Bank Support and access to sufficient units of blood and blood products.

Access to mental health and social support services

Chairman's Analysis of Process to Date

Element 1: Is continued regulation of these services necessary?

Finding: Yes (Unanimous)

Element 2: Consider the establishment of a clear needs-based methodology for the initiation of heart/lung transplant services.

Recommended Finding: The current system (fixed number for the state) is appropriate for the present time. If factors change, the regular review cycle should be able to accommodate them.

- Implication of charge element is that current standards are not based on need. There is no claim, data or testimony that there is unmet need.
- There may be open capacity at present
- Existing units have unused capacity
- In other areas "needs based" seems to equate to ""facility-based", with initiation based on performance of a particular volume of related services or patients at a facility. The nature of these services does not lend itself to such a structure.
- At present, issues extraneous to CON process constrain number of procedures performed (e.g., organ donations, national system of waiting lists and organ allocation, insurance policy preferences)

Elements 3 and 4: Consider continuation or amendment of the CAP or an alternative methodology for regulating the number of heart/lung transplant services.

Recommended Finding: Continue the CAP concept, subject to Element 5

- See discussion of Element 2, above
- No showing that current CAP structure results in unmet need

Element 5: If retention of a heart and/or lung CAP is recommended, consider modification of the number, changes is planning area designations and/or changes in the comparative review standards.

Recommended Finding: Open. Possible responses:

1. No change (maximum of 3 of each service, statewide, with existing comparative review standards)
2. Modify comparative review standards to increase weight of geographic distribution if new openings arise (e.g., by discontinuation of an existing service).
3. Split the state into 2 or more planning areas with a provision that no more than "x" services of the state-wide maximum be in any 1 area. For example, you could say the state should be split longitudinally into 2 planning areas, with a statewide maximum of 3-services, of which no more than 2 could be in one planning area. That would mean that if one of the current SEM services was discontinued, the only new service would be in the other area.

4. Either separately, or in combination with 3, above, allow for the addition of 1 or more services.

- There was testimony regarding geographic distribution of existing capacity and the suggestion that a broader distribution might give rise to increased in-state services.
- There is a question as to whether or not there is an open slot at present. If there is an open slot, there is likelihood that the geographic distribution provisions of the existing comparative review standards would address the concern.
- There is the potential that adding sites to accommodate geographic distribution would have negative impact on quality and/or cost-effective delivery within the total state system.
- There are questions as to what appropriate changes from a state-wide planning area would be (e.g., vertical and/or horizontal, population, number of breaks). Accommodating a vested interest now sets a poor precedent.