Michigan Department of Community Health (MDCH) Comments and Recommendations for Certificate of Need (CON) Review Standards Scheduled for 2009 Review Presented to CON Commission February 5, 2009

HEART/LUNG AND LIVER TRANSPLANTATION SERVICES (Please refer to MDCH staff summary of comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of heart/lung and liver transplants under CON.	Yes	Continue regulation.	
2. Increase the number of allowed heart/lung and liver transplant centers.	Yes	Appointment of a SAC to deliberate removing the cap requirement for this standard in conjunction with developing a need methodology.	
3. Potential outdated and inconsistent language in sections 4, 8, 9 and 10.	Yes	Should identify if SAC is going to review this or if the Department is going to draft changes and update the recommendation accordingly.	
4. Make technical changes and updates that provide uniformity in all CON standards, i.e., revisions to reference of online system.	Yes	Draft recommended changes.	

Recommendation: MDCH recommends appointment of a SAC to consider elimination of the cap, in conjunction with the task of developing a clear, facility based, need methodology for heart/lung and liver transplantation services. The Department further recommends that the Commission delegate authority for the Chairperson and Vice-chairperson to appoint the members of the SAC and, further, to work with the Department to draft and approve the charge.

The Department recommends that the Commission assign the responsibility to draft technical language changes to the standards to the Department. Language changes for these standards should all be moved forward to public hearing simultaneously.

HEART/LUNG AND LIVER TRANSPLANTATION

Summary of 10/16/08 Public Hearing Comments and Department Comments

Prepared by: MDCH

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<tr><th colspan="2">Considerations from 10/16/08 Public Hearing.</th></tr>
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Public Hearing Summary: The complete oral and written testimonies are included in the February 5, 2009 CON Commission meeting binders. The agencies represented were as follows:

- Gift of Life Michigan (Written): No position but request to participate in the on-going discussions regarding this standard.

- The following agencies saw no compelling need to review and/or modify the heart/lung and liver transplantation services at this time:
  - Economic Alliance of Michigan (Verbal and Written)
  - Blue Cross/Blue Shield (Verbal and Written)
  - University of Michigan Health System (Written)

- The following agencies/individuals would like the standards changed to allow for additional transplant centers. Currently, there are three in operation and they are located in Southeast Michigan. This puts the west side of the state at a disadvantage in regards to seeking care for transplant operations. The current standards only allow for three centers.
  - Spectrum Health (Written) includes letters of support from the following:
    - Representative Bill Huizenga
    - Senator Bill Hardiman
    - Representative Dave Hildenbrand
    - Representative Kevin J. Green
    - Senator Wayne Kuipers
    - Senator Mark C. Jansen
    - Representative Brian Calley
    - Representative Arlan Meekhof
    - Representative Pete Hoekstra
    - Representative Dave Agema
  - Spectrum Health – Reed City Hospital (Written)
  - C&H Holdings (Written)
  - Calvin College (Written)
  - City of Grand Rapids (Written)
  - Cook Holdings for Butterworth Hospital (Written)
  - David G. Frey (Written)
  - Fifth Third Bank (Written)
  - Gerber Memorial Heath Services (Written)
  - The Grand Rapids Press (Written)

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Policy Issues to be Addressed

Recommendations to consider:

1. The following items should be explored:
   - The number of these types of transplants performed at the centers has remained relatively stable over the last seven years (2000 to 2007). There haven't been any significant increases or decreases.
   - The limited number of specialized staff would prevent proliferation of this service.
   - Removing the cap would eliminate comparative review. This would make the standards more administratively feasible.
   - There are currently no heart/lung and liver transplant centers in west Michigan. Removing the cap would allow such transplant centers to be opened and run on this side of the state.
   - Currently, all adult heart/lung and liver transplantation centers are located in southeast Michigan, and all are meeting the volume requirement of 12 combined heart, heart/lung and lung & 12 liver transplants annually. Henry Ford performed 10 heart transplants, 12 lung transplants and 114 liver transplants and the University of Michigan performed 33 heart transplants, 22 lung transplants, and 71 liver transplants in 2007. See attached chart.

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o Grand Valley State University (Written) o THE RIGHT PLACE, INC. (Written) o Hauenstein Neurological Center (Written) o Richard M. DeVos (Written) o Helen DeVos Children's Hospital (Written) o Holland Hospital (Written) o J.C. Huizenga (Written) o Lakeland HealthCare (Written) o Meijer (Written) o Mercy Health Partners (Written) o MMPC Michigan Medical, P.C. (Written) o Michigan State University (Written) o Oaklawn Hospital (Written) o Pennock Health Services (Written) o Steelcase Inc. (Written) o Warner Norcross & Judd (Written) o West Michigan Cardiothoracic Surgeons PLC (Written) o Craig P. Web, Ph.D. (Written) • The following agency felt there were several inconsistencies and misconceptions within the heart/lung and liver transplantation services standard and offers language changes. o University of Michigan, Transplant Center (Written): ▪ Section 4(1): Combines heart, heart/lung and lung transplant programs together, with the presumption that these operations and organ transplants are done by the same team of physicians. These are actually distinct procedures, and lung transplantation in particular is performed not only by cardiac or cardiothoracic surgeons but also general thoracic surgeons. ▪ Section 8 (e): "Requires presence of cyclosporine assay availability with results available on the same day" is outdated and too specific. Immunosuppression regimens will change and are already changing. This section should include monitoring of tacrolimus levels, or be reworded to monitoring of immunosuppression drug levels including calcineurin inhibitors such as cyclosporine and tacrolimus. ▪ Section 9.1.a: Should include: pulmonologists and surgeons trained in bronchoscopy and transbronchial techniques including biopsy and stent placement. ▪ Section 9.1.b: Should read: cardiologists, pulmonologists and surgeons trained in immunosuppression techniques.	

▪ Section 9.1.c: Should include both adult and pediatric, as appropriate, cardiologists, pulmonolgists and surgeons. ▪ Section 9.1.d: Cardiac and thoracic surgeons should have demonstrated capability of successfully performing orthotopic cardiac or lung transplantation, in accordance with United Network for Organ Sharing (UNOS) guidelines. These guidelines require documentation of satisfactory training in transplantation in patient settings. Any simulation (animal or computer modeling) of human transplantation as sole criteria for establishing competency in performing transplantation would not be satisfactory for medical specialty board certification let alone UNOS certification. ▪ Section 9.1.e: "Two cardiac transplant surgical teams with a total of at least 3 trained cardiac surgeons..." is inaccurate in that, in practice, there exists a distinction between cardiac surgery, general thoracic surgery and cardiothoracic surgery. The statement as currently worded assumes that the same surgical teams perform both heart and lung transplantation and include cardiac surgeons only. There should be a separate statement regarding availability of surgical team (cardiothoracic and/or general thoracic) for lung transplantation. Not only cardiac surgeons but also general thoracic (American Board of Thoracic Surgery-certified) surgeons are capable of performing such procedures safely and with excellent outcomes. Several of the largest lung transplant programs are directed by general thoracic surgeons, most notably Dr. G. Alex Patterson at Barnes Hospital, Washington University in St Louis, MO and Dr. Shaf Keshavjee at Toronto General Hospital, Toronto Canada. Both of these general thoracic surgeons are recognized internationally as leaders and authorities not only on pulmonary transplantation but also in the field of thoracic surgery. ▪ Section 9.1.f: Should include a pathologist capable of diagnosing pulmonary allograft rejection on lung biopsy specimens. ▪ Section 9.1.g: Should include anesthesiologists trained in open heart surgery and/or general thoracic surgery. ▪ Section 9.2: Cardiac transplant survival benchmark	

should also be adjusted to what is reported in OPTN, not absolute numbers that are at risk of becoming outdated. ▪ Section 10.2.a: Should read radionuclide HIDA biliary scan, rather than nuclear HID biliary scan.	

1. Review current requirement for the number of heart/lung and liver transplant centers in Michigan. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **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. Review the current wording in sections 4 per Dr. Chang's suggestions. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **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.	
3. Review the current wording in sections 8 per Dr. Chang's suggestions. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver transplantation services** (e) a cyclosporine assay laboratory with results available on the same day;	

4. Review the current wording in sections 8 per Dr. Chang's suggestions. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung transplantation services** Sec. 9. (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; (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.	
5. Review the current wording in sections 10 per Dr. Chang's suggestions. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **Section 10. Additional terms of approval -- applicants proposing liver transplantation services** (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.	