

## MDCH Recommendations for CON Standards Scheduled for 2012 Review

| <b>Heart/Lung and Liver (HLL) Transplantation Services</b><br>(Please refer to MDCH staff summary of comments for additional detail) |                        |  |
|--|------------------------|--|
| Should services continue to be regulated under CON?  | No.                    | There is no data suggesting direct relationship between quality and volume. Additionally, financial and staffing requirements dictate concentration of the services to relatively few providers.   |
| Identified Issues  | Recommended for Review | Comments   |
| Increase the number of allowed heart/lung and liver transplant centers.  | No.                    | The number of these types of transplants performed at the centers has remained relatively stable over the last two years (2008-2010). There are not any factors to suggest any significant increases or decreases, and are constrained by the availability of organ donations. |
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### MDCH Staff Analysis of Heart/Lung & Liver (HLL) Transplantation Services Standards

#### Statutory Assignment

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the HLL Transplantation Services Standards are scheduled for review in calendar year 2012.

#### Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from five organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health System:*
  - Supports the continued regulation of HLL transplantation services.
  - Recommends the Commission consider an institution specific methodology for initiation of HLL transplantation services, in lieu of comparative review.
  
2. *Dennis McCaffery, Economic Alliance for Michigan (EAM)*
  - Supports continued regulation of HLL transplantation services.
  - States that volume is constrained by the supply of organs available for transplantation, not upon lack of providers.
  - Supports Department-only technical changes without the formation of a SAC.
  
3. *Steve Szelag, University of Michigan Health System*
  - Supports continued regulation of HLL transplantation services.

- States that it is too early to objectively evaluate the effects of the prior modification in March 2010.
  - Recommends no revisions at this time and wait until the next review cycle in 2015.
4. *Robert Meeker, Spectrum Health*
- Supports continued regulation of HLL transplantation services.
  - Recommends no revisions at this time.
5. *Karen Kippen, Henry Ford Health System*
- Supports continued regulation of HLL transplantation services.
  - Recommends no revisions at this time.

**Summary of the Covered Service and Consideration of “Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review”**

Michigan is one of 21 states which regulate Organ Transplantation Standards within CON. In 2010, there were 61 heart transplants, 0 heart/lung transplants, 42 lung transplants, and 198 liver transplants. There are currently 3 facilities that are approved to provide all of these services within the State of Michigan.

As part of the review, the Department considered the “Guiding Principles...” as follows:

HLL Transplantation Services have low capital costs. According to the most recent CON application, the facility was not close to the covered capital expenditure threshold of \$3,012,500. The capital costs to initiate this service should remain relatively low because most facilities that would seek initiation would have existing infrastructure, operating rooms, and surgical equipment to perform transplant procedures.

The operational costs involved with a functional HLL transplant program vary greatly among facilities, but all programs must include: a primary transplant surgeon, transplant physician, and transplant team composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology with the appropriate training and experience to provide transplantation services. The Department could not obtain facility specific operating cost information. Since 2009, no new applications have been submitted to establish new HLL transplant programs.

HLL Services are provided by 3 facilities within the State of Michigan. The number of these types of transplants performed at the centers has remained relatively stable over the last three years specifically: 2008 - 305 transplants performed, 2009 - 296 transplants performed, and in 2010 - 301 transplants performed.<sup>1</sup> These services are restricted to programs that participate with Organ Procurement Organizations (OPOs) and are assigned geographic service areas by CMS and are obligated to serve all hospitals in their assigned area. Under these regulations, hospitals must contract with their federally designated OPO. Hospitals may not choose which OPO to work with. The contract facilitates that transplant patients receive procedures that are of the highest quality, locally accessible, and cost-effective transplant services within their community or surrounding area.<sup>2</sup>

<sup>1</sup> CON Annual Survey Data: 2008, 2009, 2010

<sup>2</sup> <http://www.onelegacy.org/site/docs/ConditionsOfParticipationForHospitals.pdf>

HLL Services are required to be in compliance with Medicare's requirements in order to be reimbursed for the transplant. The evaluation of a program's compliance with Medicare requirements involves several steps. CMS will obtain data from United Network for Organ Sharing (UNOS), the contractor for the Organ Procurement Transplantation Network (OPTN), and from the University of Michigan to provide background and determine compliance with the program's OPTN membership, submission of forms to OPTN, clinical experience (volume), and outcomes, as applicable. CMS will share this information with either the State Survey Agency or CMS' Contractor (depending upon the provider's location) to incorporate into their onsite evaluation of compliance with the Medicare Conditions of participation.<sup>3</sup>

The current HLL Transplantation Standards do incorporate a needs-based methodology. The existing standards only allow for three (3) HLL transplantation services within a planning area (currently defined as the state of Michigan), and the cap creates a comparative review for any applicant proposing to initiate a program. There are currently 3 facilities approved to provide HLL Transplantation Services; two located in Southeast Michigan and one located on the west side of the State. Geographic access to HLL services is not compromised by CON requirements.

There is a direct relation between quality and volume as is recognized by volume standards associated with federal approvals (e.g. CMS, OPTN). Transplant centers must meet all data submission, clinical experience, and outcome requirements to receive initial approval by CMS, and they must also perform 10 transplants over a 12-month period. The transplant center's Quality Assessment and Performance Improvement (QAPI) program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, and patient education, satisfaction, and rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.<sup>4</sup>

The UNOS By-Laws require Transplant Hospitals to implement and practice appropriate routine referral procedures for all potential donors. Transplant Hospitals are further expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.<sup>5</sup> In addition, this particular service is constrained by the availability of organ donations.

### **MDCH Staff Recommendations**

- Consider deregulating HLL transplant services. The clinical services are constrained by the availability of organ donations. There is currently no indication of immediate or sustaining proliferation of these services. Quality and volume outcomes will not be affected as programs are evaluated and must comply with CMS requirements and adhere to United

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<sup>3</sup> [https://www.cms.gov/CertificationandCompliance/20\\_Transplant.asp](https://www.cms.gov/CertificationandCompliance/20_Transplant.asp)

<sup>4</sup> <https://www.cms.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>

<sup>5</sup> <http://www.unos.org/about/index.php?topic=bylaws>

Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) certification.