

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPEN MEETING NOTICE

GROUP: Heart, Lung, and Liver (HLL) Transplantation Services
Standard Advisory Committee (SAC)

DATE: Thursday, February 5, 2026

TIME: 9:30 a.m. – 11:30 a.m.

A virtual meeting will be held via Zoom.

(The SAC Chairperson(s) can choose in advance to hold a meeting in person.)

In advance of the meeting, members of the public may provide input on or ask questions related to any business that will come before the SAC by sending an email to MDHHS-ConWebTeam@michigan.gov seven days before the meeting. Take note that the SAC is a recommending body that is not governed by the Open Meetings Act. If there is no quorum, or technical difficulties prevent Zoom functionality for the public, the meeting may continue.

Join from PC, Mac, Linux, iOS or Android:

[Zoom Link](#)

Or Telephone Dial:

USA (408) 961-3927

USA (408) 961-3927

USA (408) 961-3927

USA (855) 758-1310 (US Toll Free)

Conference code: 311440

Note: The Michigan Department of Health and Human Services will provide reasonable accommodations to individuals who need auxiliary aids and/or assistance if a request is made to MDHHS-ConWebTeam@michigan.gov at least seven days before the meeting.

Check the Certificate of Need (CON) Website for future posting of Tentative Agenda
www.michigan.gov/con

Michigan Department of Health and Human Services (MDHHS or Department)
MEMORANDUM
Lansing, MI

Date: January 30, 2026

TO: Heart, Lung, and Liver (HLL) Transplantation Services Standard Advisory Committee (SAC)

FROM: Tiffani Stanton, Departmental Analyst, MDHHS
Katherine Tucker, Department Specialist, MDHHS
Justin Easter, Departmental Analyst, MDHHS

RE: February 5, 2026 – HLL SAC Meeting

This cover memo gives an overview of the meeting's agenda and the material that is included in the binder.

I. Call to Order

HLL SAC Chairperson, Dr. Sonnenday, will call the meeting to order once a quorum has been established. The 2025-2026 HLL SAC has a quorum of eight (8). *(The Department will keep track of quorum.)*

II. Declaration of Conflicts of Interest

Standard Advisory Committee members are subject to the Conflicts of Interest provisions of the Certificate of Need Commission Bylaws. Please review the Conflicts of Interest excerpt included in your electronic binder and declare any potential conflicts of interest during this agenda item.

III. Review of Agenda

This agenda item will require Committee approval. A motion and a second should be made. Once the motion is on the table, Committee members can introduce amendments. If there are no amendments, all those in favor should raise their hands first, followed by those opposed. Department staff will record the vote and announce the result.

IV. Review of Minutes of January 8, 2026

This agenda item will require Committee approval. A motion and a second should be made. Once the motion is on the table, Committee members can introduce amendments. If there are no amendments, all those in favor should raise their hands first, followed by those opposed. Department staff will record the vote and announce the result.

V. Review and Discussion of Comparative Review Section

The Committee will conduct a further review of the comparative review section of the HLL Review Standards and discuss potential revisions. Members may propose language changes, review and discuss available data, and identify any additional data sources available to support the review.

IX. Future Meeting Dates – March 5, 2026; April 2, 2026; May 7, 2026

X. Adjournment

The HLL SAC Vice Chairperson will need to take a motion and a second before the vote to adjourn can be held. After the motion has been seconded, the HLL SAC can vote by voice to adjourn the meeting.

EXCERPT FROM CON COMMISSION BYLAWS
ARTICLE IX – CONFLICT OF INTEREST PROVISIONS

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for Commission members exists when the individual member has a financial or personal interest in a matter under consideration by the Commission. The personal interest of a Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.
2. A Commission member does not violate the State Ethics Act if the member abstains from deliberating and voting upon the matter in which the member's personal interest is involved.
3. A Commission member may deliberate and vote on matters of general applicability that do not exclusively benefit certain health care facilities or providers who employ the Commission member, even if the matter involves the member's employer or those for whom the member's employer does work.
4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A Commission member must disclose any potential conflict of interest after the start of a meeting, when the Commission begins to consider a substantive matter, or, where consideration has already commenced, when a conflict or potential conflict of interest becomes apparent to the member.
2. After a meeting is called to order and the agenda reviewed, the chairperson must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.
3. A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.
4. Where a Commission member has not discerned any conflict of interest, any other Commission member may raise a concern whether another member has a conflict of interest on a matter. If a second member joins in the concern, the Commission must discuss and vote on whether the member has a conflict of interest before continuing discussion or taking any action on the matter under consideration. The question of conflict of interest is settled by an affirmative vote of a majority of those Commission members appointed and serving, excluding the member or members in question.
5. The minutes of the meeting must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

**TENTATIVE
AGENDA**

HEART, LUNG, AND LIVER (HLL) TRANSPLANTATION SERVICES STANDARD ADVISORY COMMITTEE (SAC) MEETING

Thursday, February 5, 2026
9:30 a.m. – 11:30 a.m.

[Zoom Meeting Link](#)

Telephone Dial:
(408) 961-3928 or (855) 758-1310
Meeting ID: 834 5730 8206

Agenda topics		
I.	Call to Order	Dr. Sonnenday, Chairperson
II.	Declaration of Conflicts of Interest	
III.	Review of Agenda	
IV.	Review of Minutes of January 8, 2026	
V.	Review and Discussion of Comparative Review Section	Dr. Sonnenday, Chairperson
VI.	Next Steps	Dr. Sonnenday, Chairperson
VII.	Public Comment	Katherine Tucker, MDHHS
VIII.	Future Meeting Dates – March 5, 2026; April 2, 2026; May 7, 2026	Dr. Sonnenday, Chairperson
IX.	Adjournment	
NOTE: There may be a 10-minute break at approximately 10:00 a.m.		

Be sure all cellular telephones are turned off or set to vibrate during meeting.

- NOTES:
- 1) *To be included as part of the official record, the SAC would appreciate brief and concise written copies of the oral testimony and/or other documentation/data pertaining to Public Comment items.*
 - 2) *Public Comment for all items will be limited to three (3) minutes per item per speaker per organization with a maximum of ten (10) minutes if speaking on four (4) or more items. This time may be adjusted depending on the number of speakers.*

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
HEART, LUNG, AND LIVER (HLL) TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (SAC) MEETING**

Thursday, January 8, 2026

Virtual Meeting via Zoom

DRAFT Meeting Minutes

I. Call to Order

Chairperson Dr. Christopher Sonnenday called the meeting to order at 9:31 a.m.

A. Members present:

Dr. Christopher Sonnenday – Chairperson
Dr. Damanpreet Bedi – Vice-Chairperson (*Arrived at 10:19am*)
Dr. Heather Stamat
Dr. Brian Fedoronko
Dr. Hugh Lindsey
Dr. Ammar Hassan
Dr. Ahmed Nassar (*Arrived at 9:32am*)
Dr. Deepak Venkat
Dr. Joel Stracke
Dr. John Serini
Dr. Srinivas Janardan
Jenna Beckman
Jeff Muller
Kelly Summers
Makenzie Buchert

B. Member Absent:

None

C. Michigan Department of Health and Human Services Staff Present:

Tiffani Stanton
Marcus Connolly
Ninah Sasy
Tulika Bhattacharya
Cliffaney Wilkinson
Katherine Tucker
Justin Easter

II. Declaration of Conflicts of Interest

No conflicts of interest were declared to prevent anyone from participating in the meeting.

III. Review of Agenda

Motion by Dr. Serini, seconded by Dr. Stamat to approve the final agenda as presented. All in favor.

Motion carried.

IV. Review of Minutes of December 11, 2025

Motion Dr. Serini, seconded by Mr. Muller to approve the meeting minutes of December 11, 2025. All in favor.

Motion carried.

V. Discuss Cost and Quality Gaps Related to a 4th Liver Transplant Program

Dr. Sonnenday discussed the gaps identified during the December SAC meeting as it relates to cost and quality of a 4th Liver Transplant Program.

A spreadsheet from the OPTN showing the US (adult) transplant programs from 1988 to November 2025 was presented and discussed amongst the SAC members.

VI. Heart, Lung, and Liver Transplantation Services CON Review Standard

i. Review 2024-2025 HLL SAC Working Draft

The SAC reviewed and discussed the language in the working draft from the 2024-2025 HLL SAC.

ii. Review of Public Hearing Recommendations

The SAC reviewed the comments and language recommendations that were presented from the public hearing.

iii. Discuss Proposed Language Edits and Recommendations

The SAC reviewed and discussed potential language recommendations presented by Dr. Sonnenday.

VII. Next Steps

The Chair, Dr. Sonnenday, would like to reach out to the consumer, purchaser, payers representatives offline to discuss costs of a 4th liver transplant program from their perspective.

VIII. Public Comment

Melissa Reitz, McCall Hamilton

IX. Future Meeting Dates

February 5, 2026; March 5, 2026; April 2, 2026; May 7, 2026

X. Adjournment

Motion by Dr. Janardan, seconded by Dr. Lindsey to adjourn the meeting at 11:31 AM. All in favor.

Motion carried.

Department Recommendation

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH ~~AND HUMAN SERVICES~~

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HEART/LUNG AND LIVER (HLL) TRANSPLANTATION SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for the approval and delivery of HLL services under Part 222 of the Code. Pursuant to Part 222 of the Code, heart/lung and liver transplantation are covered clinical 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. The Department shall use these standards in applying Section 22225(1) of the code, being ~~ss~~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.

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) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
- (c) "Department" means the Michigan Department of ~~Community Health~~ ~~AND HUMAN SERVICES~~ (~~MDCHMDHHS~~).
- (d) "Health service area" or "HSA" means the geographic area set forth in Appendix A.
- (e) "Licensed site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.
- (f) "Medicaid" means title XIX of the ~~ss~~Social ~~ss~~Security ~~aa~~Act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.
- (g) "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.
- (h) "Organ Procurement Organization" or "OPO" means an organ procurement organization as defined by CFR Title 42, Part ~~485.302~~ ~~486.302~~.
- (i) "Pediatric" means any patient less than ~~1815~~ years of age or any patient with congenital anomalies related to the proposed transplantation service.
- (j) "Planning area" means: ~~the state of Michigan;~~
 - (i) FOR HEART, HEART/LUNG, OR LUNG TRANSPLANTATION SERVICES, AS REFERENCED IN SECTION 4 AND SECTION 7, IS THE STATE OF MICHIGAN.
 - (ii) FOR LIVER TRANSPLANTATION SERVICES ONLY, AS REFERENCED IN SECTION 5 AND SECTION 7, IS:
 - (A) PLANNING AREA ONE THAT INCLUDES COUNTIES IN HEALTH SERVICE AREA 1 OR
 - (B) PLANNING AREA TWO THAT INCLUDES THE COUNTIES IN HEALTH SERVICE AREAS 2, 3, 4, 5, 6, 7, AND 8.
- (k) "Survival rate" means 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;

Department Recommendation

- (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.

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

Section 3. Requirements to initiate a heart, heart/lung, or liver transplantation service

Sec. 3. Initiate or implement 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).

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

- (a) operating rooms **THAT MEET APPLICABLE FACILITY STANDARDS OF THE UNITED NETWORK FOR ORGAN DONORS (UNOS) ORGAN PROCUREMENT AND TRANSPLANT NETWORK (OPTN);**
- (b) **TRANSPLANT** 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) clinical research;
- (j) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization that is an approved member of the OPTN, 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 **TO MATCH THE NEEDS FOR MASSIVE TRANSFUSION PROTOCOL;**
 - (n) **an established organ donation program, with brain death protocol, consistent with applicable Michigan law; and**
 - (o) **a written transplant agreement with Michigan's Federally designated OPO to promote organ donation at the applicant hospital;**

Commented [TS1]: Recommends removing outdated language. of 3(1) (n) & 3(1) (o)

Department Recommendation

(f) SURGICAL ICUBEDS WITH CAPACITY TO TAKE ON THE FORECASTED VOLUMES IDENTIFIED IN THE APPLICATION FOR THE SERVICE MADE AVAILABLE WHENEVER AN ORGAN BECOMES AVAILABLE;

(g) EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO);

(h) CONTINUOUS RENOVASCULAR HEMODIALYSIS (CRRT);

~~Other requirements addressed in the CON.~~

(2) An applicant proposing to initiate shall provide 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 specified time period as applicable to the proposed project. The implementation plan shall identify:

- (a) 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 physicians and support staff;
- (b) the timetable for completing each component or activity specified in subsection (a); and
- (c) the applicant shall document what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis if previously 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.

(3) An applicant(s) proposing to initiate a joint sharing arrangement for a transplantation service that 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 LOCATED WITHIN 5 MILES OF EACH OTHER** 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.~~

Commented [TS2]: Support for the changes recommended during the 24-25 SAC for 3(3) & 3(4).

(4) An application which proposes a joint sharing arrangement for a heart, heart/lung, lung or 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 4(1) or 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 LOCATED WITHIN 5 MILES OF EACH OTHER** 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;

Department Recommendation

- (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 or liver transplantation services; **AND**
- (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, heart/lung, lung or liver transplantation procedures in the second 12-months of operation following the date on which the first heart, heart/lung, lung, or liver transplant procedure is performed, and annually thereafter. **THE VOLUMES FOR THE ADULT AND PEDIATRIC TRANSPLANT PROGRAMS SHALL BE COMBINED FOR PURPOSES OF EVALUATING COMPLIANCE WITH THESE STANDARDS ONCE THE PROGRAMS ARE OPERATIONAL. IN ADDITION, EACH PROGRAM, ADULT AND PEDIATRIC MUST PERFORM AT LEAST ONE TRANSPLANT FOR EACH TYPE APPROVED (AS APPLICABLE) PER YEAR.**

(5) AN APPLICANT SHALL DEMONSTRATE THAT THE NUMBER OF EXISTING LIVER TRANSPLANTATION SERVICES DOES NOT EXCEED THREE (3) LIVER TRANSPLANTATION SERVICES IN PLANNING AREA ONE AS DEFINED IN SECTION 2(1)(i)(ii)(A) AND DOES NOT EXCEED ONE (1) LIVER TRANSPLANTATION SERVICE AS DEFINED IN SECTION 2(1)(i)(ii)(B) IN PLANNING AREA TWO AND THAT THE APPROVAL OF THE PROPOSED APPLICATION WILL NOT RESULT IN THE TOTAL NUMBER OF LIVER SERVICES EXCEEDING THE NEED FOR EACH SPECIFIC PLANNING AREA. THE APPLICANT SHOULD DEMONSTRATE THAT THE PROPOSED APPLICATION FOR LIVER TRANSPLANTATION SERVICES IS NOT FOR PEDIATRIC PATIENTS ONLY.

Commented [TS3]: Recommendations to have this language added to Section 5 instead of Section 3(5)

Section 4. Additional requirements for heart, heart/lung, or lung transplantation services

Sec. 4. (1) Approval of an application proposing to provide heart, heart/lung, or lung transplantation services shall not result in more than three (3) heart, 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 3(4) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 3(4) of these standards, an applicant for a heart, heart/lung, or lung transplantation service shall project a minimum of 12 heart, heart/lung, or lung transplantation procedures annually in the second 12-months of operation following the date on which the first heart, heart/lung or lung transplant procedure is performed and annually thereafter.

(3) An applicant proposing to provide heart, 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, 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.

Department Recommendation

- (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.

Section 5. Additional requirements for 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 **ONE, AND NO MORE THAN ONE (1) LIVER TRANSPLANTATION SERVICE IN THE PLANNING AREA TWO.** In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 3(4) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 3(4) of these standards, 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) a **SUBAREA** 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 **and**

BY A LIVER TRANSPLANT ANESTHESIA DIRECTOR WHO IS CERTIFIED BY THE AMERICAN BOARD OF ANESTHESIOLOGY, FELLOWSHIP TRAINED IN CRITICAL CARE MEDICINE, CARDIAC ANESTHESIOLOGY, OR A LIVER TRANSPLANT FELLOWSHIP INCLUDING PERI-OPERATIVE CARE OF AT LEAST 20 LIVER TRANSPLANT RECIPIENTS, OR EXPERIENCE IN THE PERI-OPERATIVE CARE OF AT LEAST 20 LIVER TRANSPLANT RECIPIENTS IN THE OR IN THE PAST FIVE YEARS POST-RESIDENCY.

(5) **AN APPLICANT SHALL DEMONSTRATE THAT THE NUMBER OF EXISTING LIVER TRANSPLANTATION SERVICES DOES NOT EXCEED THREE (3) LIVER TRANSPLANTATION SERVICES IN PLANNING AREA ONE AS DEFINED IN SECTION 2(1)(II)(A) AND DOES NOT EXCEED ONE (1) LIVER TRANSPLANTATION SERVICE AS DEFINED IN SECTION 2(1)(II)(B) IN PLANNING AREA TWO AND THAT THE APPROVAL OF THE PROPOSED APPLICATION WILL NOT RESULT IN THE TOTAL NUMBER OF LIVER SERVICES EXCEEDING THE NEED FOR EACH SPECIFIC PLANNING AREA. THE APPLICANT SHOULD DEMONSTRATE THAT THE PROPOSED APPLICATION FOR LIVER TRANSPLANTATION SERVICES IS NOT FOR PEDIATRIC PATIENTS ONLY.**

THE APPLICANT SHALL DEMONSTRATE THE FACILITY HAS A MINIMUM OF 12 SURGICAL TEAMS APPROVED FROM THE MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS PARAHEALTH FACILITIES ENGINEERING SECTION.

Commented [TS4]: Recommendation to update outdated information in Section

Commented [TS5]: Recommendations to remove as struck as a renal transplant program should already be in operations.

Commented [TS6]: Hospital subarea's is outdated terminology.

Commented [TS7]: Update this section to determine which services and programs are most relevant for a liver transplant program.

Commented [TS8]: Recommendations to move to section 5 instead of Section 3(4).

Department Recommendation

(7) PROPOSED LOCATION FOR LIVER TRANSPLANTATION PROGRAMS MORE THAN 150 TRAVEL MILES FROM THE NEAREST EXISTING TRANSPLANT PROGRAM WITHIN THE STATE OF MICHIGAN.

(8) BEFORE THE FIRST PROCEDURE IS PERFORMED, THE FOLLOWING MUST BE DEMONSTRATED:

(i) THE APPLICANT MUST IDENTIFY AT LEAST TWO TRANSPLANT HEPATOLOGISTS WHO HAVE AGREED TO OPERATE AS A TEAM TO ENSURE CONTINUOUS COVERAGE ON-SITE 365 DAYS PER YEAR, 24 HOURS PER DAY.

(ii) THE APPLICANT MUST DEMONSTRATE THE VARIOUS POLICIES, PROCEDURES, AND PROTOCOLS AS REQUIRED BY THE OPTAL.

Section 6. Requirements for Medicaid participation

Sec. 6. 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.

Section 7. Review standards for comparative reviews

Sec. 7. Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, shall be grouped and reviewed comparatively with other applications. For purposes of these standards, 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.

(1) 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.

(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform Anatomical Gift Law, Act No. 136 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.

(ab) 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:

Number of Transplant Programs in HSA	Points Awarded
Two or more programs	0
One program	2
No programs	4

Commented [TS9]: Recommendation to update outdated information in section 7. Update to ensure scoring differentiates between applicants. Any new metric should be from public data/directly from facilities.

Commented [TS10]: Recommendations to modify this section to reflect points awarded on the program with the greatest distance.

Department Recommendation

(be) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed 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. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number.

(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 nearest whole number, 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 hospital charges expressed as a percentage, rounded to the nearest whole number, as determined by the Michigan Department of Community Health and Human Services Medical Services Administration. The indigent volume data being used in this subsection is the data in the most current DCH-MSA Disproportionate Share Hospital (DSH) report at the time the application(s) is deemed submitted by the Department.

(c) 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 site at which the heart/lung or liver transplant procedures will be 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.

(d)-(h) **Recommending existing renal transplant services that will better assess an applicant's capacity to deliver high quality, cost-effective care.**

Applicants should be evaluated and scored based on – higher operating room volumes and higher case mix index (CMI).

Allocate 1 point for each DCH-approved transplant service currently in operation at the applicant site.

Points for applicants available (0) currently with higher capacity earning higher scores.

Points for existing transplant related infrastructure.

24-hour blood bank capable of renal transplantation.

Attending physicians with fellowship training and/or minimum of two years' experience in same transplant service being proposed.

Transplant team coordinator with demonstrated experience supporting pre- and post-transplant care in the same type of program.

Nurses with specialized training in the same transplant discipline.

A minimum of experience in managing patients with the same transplant specialty.

An active, formally structured multi-disciplinary research program focused on transplantation.

Points based on the average MELD score in the Health Service Area where the proposed transplant program would be located as an indicator of patient need and disease severity.

Points based on the average MELD score in the Health Service Area where the proposed transplant program would be located as an indicator of patient need and disease severity.

(2) 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 qualifying 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 by the CON administrative unit of the Department responsible for administering the CON program when an application is submitted.

Commented [TS11]: Recommendations to update this section to specifically measure Medicaid participation, granting points based on the highest number of Medicaid patient days. Measure distance to nearest existing transplantation program of the same type being applied for. Greatest distance win allotted points. Or using language similar to Psychiatric Beds review standards using the Medicaid cost report associated with an applicant hospital's NPI.

Commented [TS12]: Has this report type updated? Should this be MDHHS?

Commented [TS13]: Recommendations to clearly define pre-and post transplant care metrics to avoid ambiguous scoring. Consider measuring the number or patients receiving post-transplant care in collaboration with an existing transplant program of the same type being requested. Recommendations to state the applicant has the capability to perform the required pre- and post-transplant testing and follow-up with detailed outline of the capabilities.

Commented [TS14]: Consider other metrics such as CMS Star Ratings, (similar to Hospital beds standards), or the Scientific Registry of Transplant Recipients (SRTR) find and compare programs reported for kidney transplantation.

Department Recommendation

(3) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Consider adding criteria to help the Department determine applicant who will submit a high quality program at the lowest cost.

Section 8. Project delivery requirements -- terms of approval

Sec. 8. An applicant shall agree that, if approved, the HLL service(s) shall be delivered in compliance with the following terms of CON approval.

(1) 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.

(2) Compliance with the following quality assurance requirements:

(a) The applicant shall comply and maintain a functionally active program pursuant to OPTN and its by-laws and policies.

(i) The applicant shall comply with the Center for Medicare and Medicaid Services (CMS) standards and shall become Medicare approved within the first ~~two~~ years of implementation of services.

(ii) The applicant must be in good standing with the OPTN.

(b) The transplantation service shall have **THE FOLLOWING:**

(i) ~~a~~ transplant team leader and coordinator

(ii) ~~a~~ transplant administrator

(iii) ~~a~~ transplant social worker

(iv) ~~a~~ transplant surgeon

(v) ~~a~~ financial coordinator

(vi) ~~a~~ transplant pharmacist

(vii) ~~a~~ transplant psychologist, and

(viii) ~~other roles identified in section 3 project initiation~~

(c) 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.

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

(e) 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.

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

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

(h) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant. The applicant shall also maintain a registry of patients listed for a transplant and for transplant recipients as required by the federal OPTN.

Commented [TS15]: Update outdated information in section 8.

Consider quality assurance and access to care metrics to be included for a liver transplant program.

Commented [TS16]: Recommendation to update this section with tighter timelines, clarifying staffing requirements, updating annual survey language, requiring transplant centers to operate outreach hepatology clinics in underserved areas.

Department Recommendation

(i) 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.

(j) Compliance with the Uniform Anatomical Gift Law, pursuant to MCL Section 333.10101 et seq. of the Michigan Compiled Laws.

(3) Compliance with the following access to care requirements:

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

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

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

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

(iii) 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.

(4) Compliance with the following monitoring and reporting requirements:

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

(b) 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.

(c) The applicant shall provide the Department with timely notice stating the date on which the first transplant procedure is performed consistent with applicable statute and promulgated rules.

(d) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

(5) The agreements and assurances required by this section, as applicable, shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 9 | Documentation of projections

Sec. 9. 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 10. Effect on prior CON Review Standards; comparative reviews

Sec. 10. These CON review standards supersede and replace the CON Review Standards for Heart/Lung and Liver Transplantation Services approved by the CON Commission on March 26, 2010 JUNE 14, 2012 and effective on MAY 28, 2010 SEPTEMBER 28, 2012.

Commented [TS17]: Recommendation to update outdated provisions for CON Commission approval.

Commented [TS18]: Recommendation to update outdated language in Section 9. Update to define how liver transplant volume projections should be documented. Consider a methodology for the projection of volumes for a facility that does not currently offer the service. A new methodology should have data from publicly available sources or facility's direct data. Applicants should not be expected to provide data that they do not own or not publicly available (private data).

Commented [TS19]: Recommendation to update further establishing parameters on clear projection requirements

Department Recommendation

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

DRAFT

Department Recommendation**APPENDIX A**

Counties assigned to each health service area are as follows:

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