MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

~~(2) For purposes of Part 222, a separate CON is required for heart/lung or liver transplantation 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.~~

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) "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.~~

(~~e~~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.

(~~d~~C) "Department" means the Michigan Department of Community Health (MDCH).

(~~e~~D) "Health service area" or "HSA" means the geographic area set forth in ~~Section 9~~APPENDIX A.

~~(f) "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).~~

(~~g~~E) "Licensed site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(~~h~~F) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~i~~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.

(~~j~~H) "Organ Procurement Organization" or “OPO” means an organ procurement organization as defined by CFR Title 42, Part 485.302.

(~~k~~I) "Pediatric" means any patient less than 15 years of age or any patient with congenital anomalies related to the proposed transplantation service.

(~~l~~J) "Planning area" means the state of Michigan.

~~(m) "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.~~

(~~n~~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; (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 ~~for all applicants~~TO INITIATE A HEART, HEART/LUNG OR LIVER TRANSPLANTATION SERVICE

Sec. 3. ~~(1)~~ 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 ~~perform~~ either a heart, heart/lung, lung or liver transplantation service shall demonstrate that it offers all of the following services or ~~programs~~SPECIALTIES:

(a) operating rooms;
(b) 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;
(n) an established organ donation protocol, 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(s).

(2) An applicant PROPOSING TO INITIATE ~~must~~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 ~~specified in these standards or the CON Rules.~~ AS APPLICABLE TO THE PROPOSED PROJECT. ~~At a minimum, the~~ 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 physician and support staff;

(b) the timetable for completing each component or activity specified in subsection (a); and

(c) ~~if~~ 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 has been~~ 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~~, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis~~.

(3) An ~~application~~ APPLICANT(S) ~~which proposes~~PROPOSING TO INITIATE a joint sharing arrangement for a transplantation service ~~which~~ 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 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.

~~(4) An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currenty 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.~~

(~~5~~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 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 heart or heart/lung or lung or 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 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.

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(~~5~~4) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 3(~~5~~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.

(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. In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 3(~~5~~4) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 3(~~5~~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) an 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.

SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION

SEC. 6. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currenty 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 ~~6~~7. Review standards for comparative reviews

Sec. ~~6~~7. ~~(1)~~ Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, ~~or under these standards~~ shall be grouped and reviewed comparatively with other applications ~~in accordance with the CON rules.~~ 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.

(~~2~~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. 186 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.

(b) 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

(c) 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 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 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.

(d) 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.

(3) 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.

(4) 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.

Section ~~7~~8. Project delivery requirements -- terms of approval

Sec. ~~7~~8. ~~(1)~~ An applicant shall agree that, if approved, the HLL service(s) shall be delivered in compliance with the following terms of CON approval~~:~~.

(~~a~~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.

(~~b~~2) ~~Compliance with applicable safety and operating standards.~~

~~(c)~~ Compliance with the following quality assurance ~~standards~~REQUIREMENTS:~~, as applicable:~~

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

(~~ii~~A) The applicant shall comply and ~~remain~~ MAINTAIN a functionally active program ~~with the~~PURSUANT TO OPTN and its by-laws and policies.

(~~A~~I) The applicant shall comply with the Center for Medicare and Medicaid Services (CMS) standards and shall become Medicare approved within THE FIRST five years of implementation.of services.

(~~B~~II) The applicant must be in good standing with the OPTN.

(~~iii~~B) The transplantation service shall have a transplant team leader and coordinator.

(~~iv~~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.

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

(~~vi~~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.

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

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

(~~ix~~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.

(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) ~~(x)~~ 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.

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

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

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

~~(C) 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.~~

(~~xii~~C) The applicant shall provide the Department with ~~a~~ TIMELY notice stating the date on which the first transplant procedure is performed ~~and such notice shall be submitted to the Department~~ consistent with applicable statute and promulgated rules.

~~(xiii) 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.~~

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

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

(~~2~~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 ~~8~~9. Documentation of projections

Sec. 8. 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 ~~9~~10. ~~Health Service Areas~~ Effect on prior CON Review Standards; comparative reviews

Sec. 11. 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 25, 2010 and effective on MAY 28, 2010.

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

APPENDIX A

Counties assigned to each health service area are as follows:

HEALTH SERVICE AREA COUNTIES

Sec. 9. Counties assigned to each of the health service areas are as follows:

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

~~**Section 10. Effect on prior CON Review Standards; comparative reviews**~~

~~Sec. 10. (1) 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 9, 2004 and effective on June 4, 2004.~~

~~(21) Projects reviewed under these standards shall be subject to comparative review.~~