

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPEN MEETING NOTICE

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

DATE: Thursday, January 8, 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: 351819

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: December 30, 2025

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: January 8, 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 December 11, 2025

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

Review gaps in understanding the impact of a 4th liver transplant program. Review a spreadsheet containing OPTN data about the annual adult transplant activity for U.S programs. Discuss additional data sources needed to continue review of the charge.

VI. Review 2024-2025 HLL SAC Working Draft with Public Hearing Recommendations

Review the tentative language discussed during the 2024-2025 HLL SAC with recommendations from the July 2025 public hearing.

IX. Future Meeting Dates – February 5, 2026; 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, January 8, 2026
9:30 a.m. – 11:30 a.m.[Zoom Meeting Link](#)Telephone Dial:
(408) 961-3928 or (855) 758-1310
Meeting ID: 859 2311 4625

	Agenda topics	
I.	Call to Order	Dr. Sonnenday, Chairperson
II.	Declaration of Conflicts of Interest	
III.	Review of Agenda	
IV.	Review of Minutes of December 11, 2025	
V.	Discuss Cost and Quality Gaps Related to a 4 th Liver Transplant Program	Dr. Sonnenday, Chairperson
VI.	Review 2024-2025 HLL SAC Working Draft with Public Hearing Recommendations	Dr. Sonnenday, Chairperson
VII.	Next Steps	Dr. Sonnenday, Chairperson
VIII.	Public Comment	Katherine Tucker, MDHHS
IX.	Future Meeting Dates – February 5, 2026; March 5, 2026; April 2, 2026; May 7, 2026	Dr. Sonnenday, Chairperson
X.	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, December 11, 2025

Virtual Meeting via Zoom

DRAFT Meeting Minutes

I. Call to Order

Chairperson Dr. Christopher Sonnenday called the meeting to order at 9:32 a.m.

A. Members present:

Dr. Christopher Sonnenday – Chairperson
Dr. Damanpreet Bedi – Vice-Chairperson
Dr. Heather Stamat
Dr. Brian Fedoronko
Dr. Hugh Lindsey
Dr. Ammar Hassan
Dr. Ahmed Nassar
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. Introduction of Members of Staff

Introduction of SAC members and MDHHS staff.

III. Declaration of Conflicts of Interest

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

IV. Review of Agenda

Motion by M. Buchert, seconded by Dr. Janardan to approve the final agenda as presented. All in favor.

Motion carried.

V. Basic CON Overview

Tiffani Stanton, MDHHS, provided an overview of the CON Commission and the SAC process.

VI. Review and Discussion of Charge

Dr. Sonnenday discussed the summative statement that was presented to the CON Commission as his final report for the 2024-2025 HLL SAC. The 2025-2026 HLL SAC discussed the statement and how access was considered.

The SAC deliberated what materials could be required to complete the work for this SAC to consider analysis's for the cost and quality of a 4th liver transplant program in the state of Michigan.

VII. Next Steps

The Chair, Dr. Sonnenday, would like SAC members to bring necessary data that considers the cost and quality of a 4th liver transplant program in the State of Michigan to the next SAC meeting for member deliberations. Data can be shared with the Department to circulate to the SAC members ahead of the meeting.

VIII. Public Comment

None.

IX. Future Meeting Dates

January 8, 2026; February 5, 2026; March 5, 2026; April 2, 2026; May 7, 2026

X. Adjournment

Motion by Dr. Lindsey, seconded by M. Buchert to adjourn the meeting at 11:36 AM. All in favor.

Motion carried.

HLL CON SAC

Identified gaps in our understanding of the impact of a 4th liver transplant program

COST

1. Start-up costs for an individual institution to start a HLL transplant program
 - a. Personnel needs – new FTEs, recruitment costs
 - b. Capital investments – if necessary
 - c. Development of new services
 - d. Administrative costs of applying for and opening a new program
 - e. Institutional commitment to fund transplants until CMS approval obtained
 - f. How does the cost of initiating a transplant program compare to the cost of expanding outreach clinics from established programs?
 - g. What is contribution margin of liver transplantation to a transplant hospital?
2. Revenue lost by other state programs when a new program is initiated
3. Cost to statewide payers for an additional HLL transplant program
 - a. Does opening a new program increase overall costs of care?
 - b. Do new programs increase cost relative to established programs?
4. What costs to patients face traveling to existing transplant programs?

QUALITY

1. What is the impact of a new program on statewide transplant activity, and the activity of existing programs?
2. What is the impact of the closure of a program on statewide transplant activity, and the activity of existing programs?
3. What are the outcomes (according to SRTR Program Specific Reports) of new transplant programs relative to established programs?
4. Does a new transplant program affect the outcomes of surrounding transplant programs?
5. How does the opening of a new transplant program affect the quality of care for patients with advanced liver disease?

US (Adult) Transplants. Green = Start Program; Red = End Program	To Date	2025	2024	2023	2022	2021	2020	2019	2018	2017	2016	2015	2014
All Centers	213,426	10,764	10,886	10,125	9,002	8,735	8,404	8,345	7,687	7,483	Page 10 of 28 7,268	6,547	6,200
ALUA-TX1 University of Alabama Hospital	3,180	137	144	101	83	72	97	128	119	126	144	115	98
ARUA-TX1 UAMS Medical Center	707	42	46	52	51	45	33	43	37	33	42	30	31
AZGS-TX1 Banner-University Medical Center Phoenix	1,493	62	59	53	47	61	85	128	120	93	77	44	49
AZMC-TX1 Mayo Clinic Hospital Arizona	3,021	304	317	284	245	209	182	167	129	119	127	86	74
AZSJ-TX1 St. Joseph's Hospital and Medical Center	209	17	22	18	24	29	28	24	22	10	14	1	0
AZUA-TX1 Banner University Medical Center-Tucson	315	0	5	12	19	12	1	7	10	19	14	7	4
CACS-TX1 Cedars-Sinai Medical Center	2,326	135	136	104	102	113	97	96	112	86	79	51	46
CAGH-TX1 Scripps Green Hospital	926	11	23	26	24	22	36	28	28	36	34	40	35
CAIM-TX1 University of California Irvine Medical Center	164	0	0	0	0	0	0	0	0	0	0	0	0
CALL-TX1 Loma Linda University Medical Center	1,486	87	106	104	121	107	118	106	80	62	48	40	24
CAPM-TX1 California Pacific Medical Center-Van Ness Campus	2,343	87	89	69	64	63	60	57	57	63	60	69	62
CASD-TX1 University of California San Diego Medical Center	1,567	156	144	148	69	81	91	62	41	35	35	37	39
CASF-TX1 University of California San Francisco Medical Center	4,732	167	185	190	193	161	169	164	160	180	173	167	149
CASM-TX1 University of California Davis Medical Center	401	53	44	15	0	0	0	0	0	0	0	0	0
CASU-TX1 Stanford Health Care	2,145	147	136	135	125	103	90	81	75	94	61	55	67
CASV-TX1 St. Vincent Medical Center	205	0	0	0	0	0	0	14	0	0	0	0	0
CAUC-TX1 University of California at Los Angeles Medical Center	6,223	126	168	195	142	136	158	157	153	135	151	139	155
CAUH-TX1 Keck Hospital of USC	2,451	122	125	139	151	172	139	127	106	99	111	125	101
COPM-TX1 AdventHealth Porter	223	26	8	3	5	12	2	0	7	13	12	17	22
COSL-TX1 Presbyterian/St Luke's Medical Center	195	36	18	24	26	23	18	14	11	13	8	4	0
COUC-TX1 University of Colorado Hospital/Health Science Center	3,035	137	148	140	130	109	101	134	101	98	80	80	69
CTHH-TX1 Hartford Hospital	729	30	35	35	31	28	23	20	32	24	24	21	15
CTYN-TX1 Yale New Haven Hospital	611	34	16	29	32	25	25	28	28	18	22	27	25
DCGU-TX1 Medstar Georgetown Transplant Institute	2,054	117	108	104	104	112	105	96	92	97	84	49	79
DCGW-TX1 George Washington University Hospital	73	20	16	22	15	0	0	0	0	0	0	0	0
DCHU-TX1 Howard University Hospital	44	0	0	0	0	0	0	0	0	0	0	0	0
FLBC-TX1 Broward Health Medical Center	386	0	0	0	13	15	14	9	14	15	16	12	17
FLCC-TX1 Cleveland Clinic Florida Weston	631	86	79	52	39	28	41	54	70	52	48	49	24
FLFH-TX1 AdventHealth Orlando	1,117	93	59	59	44	54	48	62	65	64	68	62	56
FLJM-TX1 Jackson Memorial Hospital University of Miami School of Medicine	4,210	89	105	152	143	160	131	136	98	107	114	99	101
FLLM-TX1 Largo Medical Center	191	47	35	26	21	8	13	20	16	5	0	0	0
FLSL-TX1 Mayo Clinic Hospital Florida	4,517	151	170	176	144	149	142	169	146	156	157	150	157
FLTG-TX1 Tampa General Hospital	3,064	262	279	209	167	149	152	145	78	66	65	80	67
FLUF-TX1 UF Health Shands Hospital	2,400	136	142	191	101	158	84	30	30	27	30	48	46
GAEM-TX1 Emory University Hospital	3,429	167	167	104	93	132	105	139	127	125	141	141	154

GAPH-TX1 Piedmont Hospital	2,262	183	175	140	154	143	155	129	134	111	121	89	84
HIQM-TX1 The Queen's Medical Center	227	27	23	17	18	17	16	13	11	17	17	13	15
HISF-TX1 Hawaii Medical Center East	192	0	0	0	0	0	0	0	0	0	0	0	0
IAIV-TX1 University of Iowa Hospitals and Clinics Transplant Programs	996	12	9	16	22	19	32	32	29	22	23	23	30
ILLU-TX1 Loyola University Medical Center	1,086	76	62	76	80	68	83	65	63	51	64	50	40
ILNM-TX1 Northwestern Memorial Hospital	2,866	161	138	138	107	109	100	102	106	98	90	85	108
ILPL-TX1 Rush University Medical Center	1,928	59	65	51	41	38	45	38	24	32	32	25	16
ILUC-TX1 University of Chicago Medical Center	1,665	76	99	88	76	70	67	48	34	26	22	21	23
ILUI-TX1 University of Illinois Medical Center	1,181	40	63	59	51	56	66	51	51	40	19	21	19
INIM-TX1 Indiana University Health	3,787	173	204	181	152	161	127	144	145	139	148	139	138
INIU-TX1 Indiana University Medical Center	306	0	0	0	0	0	0	0	0	0	0	0	0
KSUK-TX1 University of Kansas Hospital	1,970	54	58	51	54	50	45	80	79	90	97	87	106
KYJH-TX1 Jewish Hospital	1,062	11	16	22	15	22	18	20	28	38	43	32	44
KYUK-TX1 University of Kentucky Medical Center	1,295	72	78	68	66	71	52	47	55	41	36	40	42
LAOF-TX1 Ochsner Foundation Hospital	3,723	119	120	114	131	143	163	203	207	182	212	229	188
LASB-TX1 Lindy Boggs Medical Center	103	0	0	0	0	0	0	0	0	0	0	0	0
LATU-TX1 Tulane Medical Center	723	34	19	13	14	17	23	16	22	21	16	20	20
LAWK-TX1 Willis-Knighton Medical Center	499	11	13	9	10	14	10	20	18	26	12	5	8
MABI-TX1 Beth Israel Deaconess Medical Center	1,096	111	125	113	79	47	37	41	32	34	32	22	34
MAHS-TX1 Beth Israel Deaconess Medical Center West Campus	426	0	0	0	0	0	0	0	0	0	0	0	0
MALC-TX1 Lahey Clinic Medical Center	1,785	96	128	109	70	78	81	85	86	101	93	70	45
MAMG-TX1 Massachusetts General Hospital	1,862	193	78	84	95	86	75	77	79	72	74	62	61
MANM-TX1 Tufts Medical Center	715	40	20	5	0	0	0	0	0	0	0	0	0
MAUM-TX1 UMass Memorial Medical Center	1,169	58	59	55	51	62	81	66	66	57	72	57	44
MDJH-TX1 Johns Hopkins Hospital	2,457	115	113	118	121	134	104	113	115	99	122	95	84
MDUM-TX1 University of Maryland Medical System	2,116	80	84	91	105	97	87	94	112	161	169	146	115
MIBH-TX1 Corewell Health William Beaumont University Hospital	394	43	31	44	41	32	20	31	30	29	14	13	16
MIHF-TX1 Henry Ford Hospital	2,776	165	121	125	104	102	93	115	96	110	112	94	81
MIUM-TX1 University of Michigan Medical Center	2,663	118	118	89	68	80	68	77	77	76	64	51	68
MNMC-TX1 Mayo Clinic Hospital Minnesota	3,712	146	135	139	123	119	131	106	103	124	127	114	100
MNUM-TX1 University of Minnesota Medical Center, Fairview	2,096	112	121	122	96	107	68	77	62	70	65	71	63
MOBH-TX1 Barnes-Jewish Hospital	2,994	133	164	130	135	151	123	114	114	120	80	98	93
MOLH-TX1 St Luke's Hospital of Kansas City	239	20	18	23	18	27	26	24	22	18	11	9	0
MOSL-TX1 SSM Health Saint Louis University Hospital	1,187	35	42	26	42	27	32	35	30	32	33	30	20
MSUM-TX1 University of Mississippi Medical Center	520	34	62	45	50	48	37	51	46	35	40	29	23
NCCM-TX1 Carolinas Medical Center	1,665	113	112	84	79	77	73	79	78	74	66	61	50
NCDU-TX1 Duke University Hospital	2,203	170	160	149	113	108	99	128	78	87	82	65	57

NCMH-TX1 University of North Carolina Hospitals	1,320	43	44	40	22	35	35	38	42	38	36	30	35
NEUN-TX1 The Nebraska Medical Center	3,245	141	133	117	94	94	105	89	70	81	74	77	76
NJLL-TX1 Virtua Our Lady of Lourdes Hospital	350	32	42	34	19	18	11	11	13	23	9	1	10
NJUH-TX1 University Hospital	1,746	37	52	46	37	41	33	45	37	5	40	48	45
NMAQ-TX1 University Hospital, University of New Mexico Health Sciences Center	57	0	0	0	0	0	0	0	0	0	0	0	0
NYCP-TX1 NY Presbyterian Hospital/Columbia Univ. Medical Center	2,468	113	116	120	100	94	72	63	53	58	74	92	121
NYFL-TX1 Strong Memorial Hospital, University of Rochester Medical Center	2,216	82	72	65	75	91	89	56	41	42	36	29	22
NYMA-TX1 Montefiore Medical Center	619	38	39	41	52	47	47	55	39	39	38	30	44
NYMS-TX1 Mount Sinai Medical Center	4,861	144	171	172	184	170	164	127	135	126	120	106	98
NYNS-TX1 North Shore University Hospital/Northwell Health	439	136	107	116	65	8	6	1	0	0	0	0	0
NYNY-TX1 New York-Presbyterian Hospital/Weill Cornell Medical Center	645	77	83	77	58	59	64	62	53	47	29	12	0
NYUC-TX1 NYU Langone Health	1,994	101	115	86	100	52	45	54	54	45	44	19	26
NYWC-TX1 Westchester Medical Center	1,255	76	70	64	68	82	65	39	43	20	21	21	22
OHCC-TX1 The Cleveland Clinic Foundation	4,005	265	251	232	207	203	163	152	147	137	149	121	126
OHCO-TX1 University of Toledo Medical Center	25	0	0	0	0	0	0	0	0	0	0	0	0
OHOU-TX1 Ohio State University Medical Center	2,138	161	194	184	150	138	148	140	113	104	58	29	34
OHUC-TX1 University of Cincinnati Medical Center	2,461	129	158	181	142	148	142	133	115	105	107	89	73
OHUH-TX1 University Hospitals of Cleveland	830	68	65	26	13	20	19	24	19	23	12	26	16
OKBC-TX1 Integris Baptist Medical Center	1,832	83	104	111	93	86	80	52	52	55	40	33	43
OKMD-TX1 OU Medical Center	321	29	38	52	50	39	5	4	0	1	19	11	12
ORUO-TX1 Oregon Health and Science University	1,579	82	91	90	58	63	72	58	57	61	63	45	43
ORVA-TX1 VA Portland Health Care System	644	17	15	17	16	20	16	18	25	22	19	22	19
PAAE-TX1 Albert Einstein Medical Center	1,538	77	76	66	61	58	70	72	64	76	70	56	41
PAAG-TX1 Allegheny General Hospital	611	60	72	61	42	44	42	43	43	28	31	25	23
PAGM-TX1 Geisinger Medical Center	250	25	19	11	13	8	10	22	12	18	11	9	10
PAHE-TX1 Penn State Milton S Hershey Medical Center	467	0	5	7	7	11	14	28	30	19	20	32	28
PAHM-TX1 Hahnemann University Hospital	242	0	0	0	0	0	0	7	11	17	23	22	21
PALV-TX1 Lehigh Valley Hospital	22	22	0	0	0	0	0	0	0	0	0	0	0
PAPT-TX1 University of Pittsburgh Medical Center	6,827	131	146	138	119	119	149	126	108	112	87	68	64
PARH-TX1 Reading Hospital	3	0	0	0	0	2	1	0	0	0	0	0	0
PATJ-TX1 Thomas Jefferson University Hospital	1,767	75	90	70	74	87	83	89	82	81	66	55	49
PATU-TX1 Temple University Hospital	216	5	6	8	3	10	14	11	8	5	12	10	10
PAUP-TX1 Hospital of the University of Pennsylvania	3,932	164	157	161	167	150	129	134	133	125	134	141	117
PAVA-TX1 VA Pittsburgh Healthcare System	1,032	10	19	24	24	16	37	45	38	40	39	33	25
PRSJ-TX1 Auxilio Mutuo Hospital	487	34	39	29	32	33	29	42	32	35	40	50	43
SCMU-TX1 Medical University of South Carolina	2,075	157	141	45	70	71	56	75	74	90	65	62	66
SCPG-TX1 Prisma Health Greenville Memorial Hospital	10	10	0	0	0	0	0	0	0	0	0	0	0

SDMK-TX1 Avera McKennan Hospital	53	0	0	0	4	6	14	12	8	8	1	0	0
TNMH-TX1 Methodist University Hospital	2,190	44	71	89	98	106	119	104	105	117	118	129	117
TNUT-TX1 William F Bowld Hospital University of Tennessee Medical Center	467	0	0	0	0	0	0	0	0	0	0	0	0
TNVU-TX1 Vanderbilt University Medical Center	3,124	163	186	152	144	114	133	126	119	134	149	130	152
TXAS-TX1 Baylor Scott and White All Saints Medical Center-Fort Worth	789	49	46	41	42	45	57	48	38	33	15	8	19
TXBC-TX1 University Hospital, University of Texas Health Science Center	2,615	164	158	142	131	115	113	113	99	76	68	85	58
TXHD-TX1 Medical City Dallas Hospital	99	46	32	19	2	0	0	0	0	0	0	0	0
TXHH-TX1 Memorial Hermann Hospital, University of Texas at Houston	1,049	2	3	30	22	26	24	26	29	31	54	45	40
TXHI-TX1 CHI St. Luke's Health Baylor College of Medicine Medical Center	1,722	107	118	88	82	70	92	82	74	91	101	69	57
TXHS-TX1 Methodist Specialty and Transplant Hospital	1,089	62	67	63	68	72	66	55	44	59	64	53	44
TXJS-TX1 University of Texas Medical Branch at Galveston	179	0	0	0	6	12	21	17	22	15	16	0	0
TXMC-TX1 Methodist Dallas Medical Center	1,338	61	81	64	73	61	73	98	54	66	67	55	56
TXMH-TX1 Houston Methodist Hospital	3,014	313	293	249	223	182	173	151	147	121	112	116	85
TXSP-TX1 UT SW Medical Center/William P. Clements Jr. University Hospital	1,215	114	128	114	104	118	112	115	95	57	45	44	42
TXTX-TX1 Baylor University Medical Center	4,450	110	114	79	81	74	82	102	112	116	129	118	90
TXVA-TX1 Michael E. DeBakey VA Medical Center	202	12	17	12	9	4	9	12	17	21	12	8	12
TXWH-TX1 Wilford Hall Medical Center	187	0	0	0	0	0	0	0	0	0	0	0	0
UTLD-TX1 Intermountain Medical Center	1,925	208	189	182	104	94	79	53	39	52	37	44	38
UTMC-TX1 University of Utah Medical Center	677	42	50	54	64	43	42	34	46	40	39	34	37
VAFH-TX1 Inova Fairfax Hospital	336	0	0	0	0	0	0	0	0	0	0	0	0
VAMC-TX1 VCU Health System Authority, VCUMC	2,581	184	189	205	168	164	134	86	78	85	49	54	51
VAUV-TX1 University of Virginia Health Sciences Center	2,078	87	76	75	79	80	77	104	91	66	64	55	59
WASM-TX1 Swedish Medical Center	556	94	76	68	45	31	26	33	51	31	28	23	19
WAUW-TX1 University of Washington Medical Center	3,048	104	108	145	114	116	117	114	90	86	80	90	88
WISE-TX1 Froedtert Memorial Lutheran Hospital	1,060	56	53	41	17	16	40	26	28	24	37	25	36
WISL-TX1 Aurora St. Luke's Medical Center	576	3	12	17	17	28	28	27	24	27	34	36	42
WIUW-TX1 University of Wisconsin Hospital and Clinics	3,080	123	109	122	112	102	113	98	112	120	103	96	82

2013	2012	2011	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993	1992	1991	1990	1989	1988
5,921	5,731	5,806	5,731	5,748	5,706	5,889	6,074	5,875	5,591	5,127	4,777	4,593	4,412	4,204	3,928	3,617	3,553	3,428	3,099	2,918	2,569	2,452	2,178	1,748	1,305
95	108	100	115	99	98	88	75	81	71	81	62	74	94	84	100	70	76	66	53	37	31	24	22	9	3
36	19	16	27	31	28	26	24	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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159	144	180	164	168	196	201	216	169	151	159	151	169	162	167	174	203	204	190	202	197	202	173	121	96	90
80	84	60	59	39	38	49	54	92	81	67	71	69	41	24	13	10	3	0	0	0	0	0	0	0	0
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146	165	164	166	166	170	165	216	246	245	171	167	174	141	95	53	0	0	0	0	0	0	0	0	0	0
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137	111	93	95	101	64	67	77	86	104	70	66	64	59	68	67	72	56	73	72	87	36	31	28	19	31

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13	18	10	14	11	12	8	12	5	9	7	4	3	1	0	0	0	0	0	0	0	0	0	0	0	0	
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85	95	103	91	103	107	128	101	143	100	84	98	147	153	160	173	169	161	192	155	160	146	133	94	51	12	
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33	27	41	39	64	56	63	73	64	68	68	71	76	76	76	70	67	59	50	37	33	21	17	4	0	0	
18	24	19	26	37	60	66	86	78	87	52	28	9	22	15	19	17	1	0	0	0	0	0	0	0	0	
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62	48	36	41	34	40	43	41	42	62	84	21	34	41	35	41	30	33	36	30	40	37	19	2	4	3	
9	23	24	21	21	14	25	22	16	15	16	18	21	27	32	22	41	27	21	22	11	13	18	12	7	1	
33	43	52	45	46	52	67	51	56	55	56	41	37	41	45	50	37	39	47	52	51	4	0	0	0	0	
11	11	13	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	13	9	1	0	0	0	
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32	15	15	25	33	30	23	36	48	59	42	51	50	42	59	45	58	44	17	3	14	9	1	0	0	0	
23	15	21	16	9	11	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
11	10	9	12	12	13	11	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
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63	62	71	125	126	106	183	182	222	242	275	179	132	148	149	153	186	177	207	219	307	289	353	465	437	402	
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53	44	53	52	38	51	47	41	21	20	20	35	34	32	33	33	35	40	33	33	20	23	17	19	21	18	
18	19	24	19	17	0	0	0	0	0	0	0	0	2	9	6	0	0	0	0	0	0	0	0	0	0	0
134	125	133	115	125	136	105	115	135	133	115	120	88	92	109	85	73	64	47	19	20	30	29	27	31	15	
44	48	38	40	46	31	38	53	56	42	19	21	19	11	10	6	11	7	19	26	20	21	29	16	10	1	
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73	55	71	76	60	61	56	66	41	37	35	52	73	66	63	39	28	35	22	32	26	19	14	3	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

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 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 **ssSocial sSecurity aAct**, 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;

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- (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)

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(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;

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- (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~~
- (vii) 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(1)(A) AND DOES NOT EXCEED ONE (1) LIVER TRANSPLANTATION SERVICE AS DEFINED IN SECTION 2.1(1)(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.**

(6) APPLICANT SHALL DEMONSTRATE THE FACILITY HAS A MINIMUM OF 12 SURGICAL BEDS APPROVED FROM THE MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS (PARA HEALTH 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 new potential 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 cross transfusion.

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 demonstrated 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.

(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