

July 29, 2025

Dr. Amy Milewski, MD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

RE: Heart, Lung, and Liver (HLL) Transplantation Review Standards

Commissioner Milewski,

On behalf of Corewell Health and our Transplant Team—and in frequent contact with HLL Transplantation Standards Advisory Committee (SAC) Vice Chair, Dr. Daman Bedi—we appreciate the opportunity to offer written comments regarding the proposed changes to the Certificate of Need (CON) review standards for HLL Transplantation Services. Our health system is broadly supportive of the SAC's recommendations under Charge 2, particularly the proposed revisions to Sections 3(3) and 3(4). However, we must express strong concerns regarding the recommendations from Charge 1.

As the SAC Chair discussed at the June Commission meeting, the SAC focused nearly all its efforts evaluating one aspect of access to liver transplant services and insufficiently assessed cost and quality. This has resulted in a recommendation that has not properly addressed the cost and quality implications. Moreover, we believe access has been reduced to travel time to a transplant center as the primary metric, when our peers at Henry Ford have demonstrated that it is distance to liver care clinics that affect outcomes, NOT distance to a transplant site. While travel time for major procedures is a useful consideration, the SAC's proposal has failed to adequately analyze two foundational, required pillars of Michigan's CON framework: cost and quality of care.

A fourth program would impose financial burdens on Michigan taxpayers and patients statewide through higher insurance premiums and other spillover economic consequences. With \$1 trillion in federal cuts to health care from recently enacted legislation and the 2026 Medicare Proposed Rules imposing further penalties and claw backs that target hospitals, Michigan cannot afford to unwisely allocate its shrinking health care budget. Health care financing exists in a starkly different situation from when the SAC's deliberations occurred. And as SAC members have expressed, this recommendation could have detrimental effects on clinical quality—both at the proposed site and existing centers. Liver transplants are limited by the availability of donors and qualified surgeons, not the number of transplant programs, per se. This recommendation would lead to patients being sicker before transplant at the new site and health systems poaching the limited expert surgeons and specialty-trained nurses from one another at existing sites—just as provider recruitment has become significantly more challenging. Now is the wrong time to move forward.

If the Commission is to consider expanding liver transplant services, we must take the time to do this in a thorough, responsible, data-driven way that achieves greater consensus. A good process should make evidence-based cost and quality projections. It should also modernize and strengthen the CON review standards, specifically provisions in Sections 3, 5, 7, 8, and 9—areas that are currently outdated and underdeveloped. Our team has outlined specific areas of concern and recommendations for improvement below.

Section 3: Initiation Requirements

The requirements for all applicants proposing to initiate a new transplantation service found in Section 3(1) should be updated for consistency with the United Network for Organ Sharing (UNOS) requirements, including the current requirement that an applicant have operating rooms onsite that meet up-to-date UNOS facility standards for operating rooms¹.

In addition, the SAC proposes new language in Section 3(5) which applies only to liver transplantation applicants, increasing the number of liver transplant programs allowed, and clarifying that an application must include adult transplantation. This is aligned with the SAC recommendations but is misplaced. Section 3 of the standards is for criteria applying to ALL transplant program applicants, not just liver transplant. This language should be moved to Section 5 of the standards, which is exclusive to applicants for liver transplant programs only.

Section 5: Liver Transplantation Requirements

The requirement in Section 5(3) tying new liver transplant programs to renal transplant centers via a written agreement with a renal transplant program located in the same “hospital subareas” is based on outdated terminology and outdated policy. A liver transplant program applicant should be required to *already* be operating a renal transplant program at the same site as the proposed liver transplant program. This requirement would align Michigan’s CON standards to best practices in liver transplantation as the clinical and scientific leaders in the transplant field have established.

Section 5(4) should also be modified to add a requirement that applicants have 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 10 liver transplant recipients; or experience in the peri-operative care of at least 20 liver transplant recipients in the OR in the past 5 years post-residency. This modification is consistent with OPTN requirements.

Section 7: Comparative Review Criteria

Several existing criteria do not adequately differentiate among applicants, are outdated, and/or are irrelevant:

- a) Reporting of deaths (Section 7(1)(a)) does not correlate to success in starting a liver transplant program and should be removed.
- b) Section 7(1)(b) should be modified to instead measure proximity to existing transplant programs of the same type, awarding points to the program with the greatest distance as it indicates the greatest improved geographic access, which is the focus and desired outcome of the SAC’s recommendation.
- c) Indigent care criteria (Section 7(1)(c)) should be updated to specifically measure Medicaid participation, granting points based on the highest number of Medicaid patient days. This update would advance Michigan’s interest in lowering health disparities.
- d) Pre- and post-transplant care metrics must be clearly defined to avoid ambiguous scoring. We recommend measuring the number of patients receiving post-transplant care in collaboration with an existing transplant program of the same type being requested.

¹ “OPTN management and membership policies. HRSA. OPTN Membership Requirements – Appendix D Available at <https://optn.transplant.hrsa.gov/policies-bylaws/optn-management-and-membership-policies/>

The care should have to be provided within 3 years post-transplant and within 3 years of application.

- e) New criteria should be introduced to better assess an applicant's capacity to deliver high-quality, cost-effective care. To effectively achieve the foundational goal of greater access, applicants should be evaluated and scored on demonstrating at least the following two criteria:
1. **Higher operating room volumes**
 2. **Higher case mix index (CMI)**

From the substantive nature of these recommended changes to the Comparative Review Criteria (which only represent what is top of mind), we believe **a majority-expert SAC is critical to ensure thorough vetting of new criteria are and that a fourth liver transplant program adds value, maintains excellent care standards, and improves health disparities** on a full range of demographic factors, including patient location.

Section 8: Project Delivery

We recommend tightening timelines (e.g., Medicare approval within 3 years), clarifying staffing requirements, updating annual survey language, and requiring transplant centers to operate outreach hepatology clinics in underserved areas to enhance statewide access and better serve patients in greater unmet needs for care.

Section 9: Projections

Volume projections must be based on standardized methodologies with clear documentation requirements, as other CON standards have specified. A reconstituted SAC should help establish these parameters.

Given the breadth and complexity of these proposed changes, we strongly recommend reconvening a Standards Advisory Committee to refine and modernize the review standards. This work should include a deeper analysis of cost, quality, and equitable access—not simply proximity to existing services.

Thank you for considering our perspective. We remain committed to improving transplant access in Michigan and welcome the opportunity to support the Commission's future deliberations.

Sincerely,



Adam M. Mix
Director, Transplant Programs
Corewell Health Grand Rapids Hospitals



Jesse J. Syring, MSA, BSN, RN, CCTC
Director, Transplant Programs
Corewell Health William Beaumont University Hospital



July 29, 2025

Dr. Amy Milewski, MD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Milewski,

On behalf of the Detroit Medical Center, I welcome the opportunity to provide written comments regarding the changes to the CON Review Standards for Heart, Heart/Lung, and Liver Transplantation Services recently proposed by the Standards Advisory Committee (SAC). As you likely know, Children's Hospital of Michigan operates a heart and liver transplant program in conjunction with Henry Ford Hospital under a joint sharing arrangement per Section 3(4) of the current standards. Children's Hospital of Michigan values the opportunity to participate in the SAC through representation by Makenzie Buchert, our Director of Transplant Services.

The DMC greatly appreciates the SACs unanimous support of our proposal to modify Sections 3(3) and 3(4) under Charge 2, to update the provisions for joint sharing arrangements to be consistent with updated Organ Procurement & Transplantation Network (OPTN) requirements and to ensure a standardized statewide approach to maintenance volume requirements for pediatric transplant programs. These changes will help to ensure continued access to pediatric transplantation in Michigan.

At the same time, however, we have grave concerns with the recommendations of the SAC related to Charge 1 which asked the SAC to "Review the liver transplantation access issues based on geography and socioeconomic factors and determine if there is substantive evidence to support the expansion of liver transplantation services. If there is support to expand liver transplantation services, work with the Department to draft edits to the CON Standards to address the access issues." As Ms. Buchert shared during the SAC process, the SAC ran out of time and did not complete their work. Though a slim majority of the SAC voted in support of adding a fourth liver transplant program based on their review of geography and socioeconomic factors, they did not consider cost or quality factors in their deliberations which was a requirement of the charge. In addition, the proposed changes in the standards considered by the SAC were inadvisably limited to language that added the fourth program and did not discuss initiation requirements for that program, nor how multiple applicants should be scored in a comparative review. The SAC also failed to review the project delivery requirements – the rules by which this fourth liver transplant program will have to operate. Given that, to our best

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knowledge, these provisions have not been updated for a considerable period, it would be inappropriate to proceed with the addition of a fourth liver transplant program without first conducting a comprehensive review of the existing provisions.

We strongly believe that a SAC, with its majority expert membership, would be the most appropriate mechanism for making the extensive updates needed to the standards. But given the hesitation of the Commission in June to form a SAC, we are providing our initial thoughts regarding updates that are needed as follows:

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

Section 3(1) specifies services and specialties any heart, heart/lung, or liver transplant CON applicant must demonstrate it offers. However, this list is outdated and some items overlap with CMS requirements. Therefore, we would recommend deleted Section 3(1)(n) and 3(1)(o).

Section 5. Additional requirements for liver transplantation services

Section 5(3) currently requires applicants for a liver transplant program to either operate a kidney transplant service or hold a written agreement with a kidney transplant service located in the same “hospital subarea.” The intent is to ensure that renal transplant expertise is readily accessible to the proposed liver transplant program. However, this terminology is outdated. Michigan’s CON program phased out the use of “hospital subareas” over a decade ago, when the hospital bed need methodology was revised. At that time, the practice of grouping hospitals into larger geographic subareas was eliminated in favor of “hospital groups,” which are reflective of overlapping market share, not geographic areas.

Liver transplant patients often present with simultaneous kidney transplant needs. When these services are located at separate facilities—even if nearby—it creates clinical inefficiencies and poses challenges to patient care. Therefore, we recommend that applicants for liver transplant programs be required to operate an established kidney transplant program at the time of application. Additionally, the kidney transplant program at the applicant facility should offer adult and/or pediatric services, consistent with the type of liver transplant program being proposed.

Section 5(4) details the services and programs that a liver transplant applicant must demonstrate they offer as a part of their application, however, the current list is outdated. We recommend adding a Director of Liver Transplant Anesthesia, consistent with OPTN requirements. ✘

Section 7. Review standards for comparative reviews

Section 7(1)(a) ranks applicants based on the percentage of deaths reported to the OPO and MDHHS, assigning nearly one-third of the total possible points to the applicant with the highest reporting rate. As timely reporting is a CMS requirement for any hospital participating in public funding, it should not be a criterion for comparing applicants and should be removed.

Section 7(1)(b) currently awards points based on the number of existing transplant programs within the planning area. However, under the SAC’s proposed framework, this metric would fail to differentiate among applicants — defeating the purpose of comparative review, which is to distinguish between them meaningfully. Moreover, this criterion carries significant weight, accounting for 4 points or roughly 29% of the total available. To better serve its purpose, we recommend revising this criterion to evaluate the distance to the nearest existing transplant program of the same type being applied for. Under this approach, the applicant located farthest from an existing program would receive the full point allocation.

Section 7(1)(c) evaluates applicants based on the volume of indigent care provided at their facility and references the “DCH-MSA Disproportionate Share Hospital (DSH) report.” However, it’s unclear whether this reference is still valid. Historically, “DCH” referred to the Department of Community Health, which has since merged into the Michigan Department of Health and Human Services (MDHHS). This shift suggests the citation may be outdated. In addition, more recent updates to comparative review standards have replaced references to “indigent volumes” with measures of Medicaid patient volume. We’re concerned that the current language may no longer reflect implementable or relevant criteria. This provision accounts for 4 points — approximately 29% of the total — so it warrants close scrutiny. While Medicaid participation should remain a heavily weighted factor, we recommend re-examining and possibly revising this criterion to ensure accuracy and applicability.

Section 7(1)(d) awards points to applicants who have provided pre- and post-transplant care to at least 15 patients over the past three years. However, without a defined standard for what constitutes pre- or post-transplant care — or how proximate to the transplant these services must be — nearly any interaction with a transplant recipient, such as an emergency department visit, could qualify. This lack of specificity risks allowing all applicants to meet the criterion, undermining its purpose as a differentiator in the CON evaluation process. We would instead recommend this criterion be updated to award points if the applicant facility already has an established hepatologist who is fellowship-trained in transplant hepatology.

In addition to revising the existing comparative review criteria, we urge the Commission to consider introducing new measures that would help the Department assess which applicants are best positioned to establish a high-quality transplant program at the lowest cost. To that end, we propose the inclusion of the following criteria:

- **Existing Transplantation Services:** Allocate one point for each CON-approved transplant service currently in operation at the applicant site.
- **ICU Capacity:** Assign points based on the applicant’s available ICU capacity, with higher capacity earning higher scores.
- **Support Services and Personnel Already in Place:** Award points for existing transplant-related infrastructure and staff at the applicant facility, including:
 - A 24-hour blood bank capable of handling mass transfusions
 - Attending physicians with fellowship training and/or a minimum of two years' experience in the same transplant service being proposed
 - A 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 pharmacist experienced in managing patients within the same transplant specialty
- An active, formally structured multi-disciplinary research program focused on transplantation
- **Community Need:** Evaluate and award points based on the average MELD score for the Health Service Area where the proposed transplant program would be located, as an indicator of unmet need and disease severity.

Section 8. Project delivery requirements – terms of approval

The project delivery requirements establish the framework for how CON holders must implement their projects and operate new services. Updating these longstanding provisions prior to approving a new liver transplant program is the Commission’s sole opportunity to ensure compliance with current guidelines and standards. It also offers a chance to promote outreach to surrounding communities, supporting broader access beyond the immediate area served by the new program. Accordingly, we recommend the following modifications and additions to Section 8:

Section 8(2)(a)(i) requires that approved applicants obtain Medicare certification within five years of beginning operations. However, access for Medicare transplant patients remains limited until this approval is secured — and they represent a significant portion of the transplant population. To more effectively expand access and uphold program accountability, we recommend reducing this timeline to three years.

Section 8(2)(b) requires transplant programs to designate a transplant team leader and coordinator. To ensure comprehensive support and effective operations, we recommend expanding this staffing requirement to include a transplant administrator, a transplant social worker, and a psychologist. These roles are critical for addressing the clinical, emotional, and logistical needs of transplant patients throughout the continuum of care.

Section 8(4)(b) mandates that approved applicants participate in the CON annual survey and identifies specific data that may be requested by the Department. While this language is consistent with other CON review standards, the current version includes an outdated provision requiring CON Commission approval for any “other data” requests not explicitly listed. Historically, the Commission has not played a role in approving Department data requests, indicating that this clause is misaligned with actual practice and should be revised accordingly. As demonstrated throughout this document, the updates required to these standards are substantial. While we have shared Detroit Medical Center’s perspective on how revisions could be implemented, we believe the most constructive path forward is to establish a new Standards Advisory Committee to carry on the work initiated by the previous SAC. Given the complexity and significance of these proposed changes, a diverse group of transplantation experts should have the opportunity to engage in meaningful dialogue, evaluate alternatives, and collectively

shape recommendations for the Commission prior to further advancement through the CON process.

We also urge the Commission to charge this Committee with evaluating the cost and quality impact of introducing a fourth liver transplant program in Michigan and exploring other approaches to expanding access across the state.

Thank you for the opportunity to share our concerns and recommendations. We would welcome the chance to actively participate in any future discussions on this important issue.

Respectfully,

Signed by:


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Brittany Lavis
Group Chief Executive Officer

July 29, 2025

Dr. Amy Milewski, MD
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Dear Commissioner Milewski,

Henry Ford Health (HFH) would like to offer comments on the Certificate of Need review standards for Heart/Lung and Liver Transplant Services:

Henry Ford Health (HFH) supports the SAC recommendations in response to Charge 2 – specifically the proposed changes to Section 3(3) and 3(4). However, we have significant concerns with the recommendations in response to Charge 1. As documented in the attached materials shared with the Commission prior to the June Commission meeting, we do not agree with the SAC's conclusion that an access problem exists in HSA 4 and disagree that a 4th liver transplant program is warranted in the Grand Rapids area. At most, a convenience issue exists in HSA 4, and adding a 4th program in that area merely improves convenience to patients who already have comparable access to liver transplant as patients living in HSA 1, where the current transplant programs exist. There are other areas of the State where the data could be interpreted to indicate a true access problem, such as the Saginaw/Midland/Bay City/Flint area (HSAs 5 and 6) as well as both the northern lower peninsula (HSA 7) and the upper peninsula (HSA 8). However, the language presented to the Commission in June does nothing to address access in those areas.

Some may look at the proposed definition of planning area for liver transplant applications and argue that the proposal would allow for a 4th program to be placed anywhere outside of HSA 1, but when you look at the rest of the initiation criteria in Section 5 you will see that, in fact, Section 5(3) limits the new program to only the same "hospital subarea" as an existing renal transplant program. If you are not aware, there are only two existing renal transplant programs in Michigan outside of HSA 1 and those are both in downtown Grand Rapids. So, without further modifications to Section 5, the recommendations of this SAC will do nothing to address access in parts of the state that arguably have a greater need.

In addition, the SAC acknowledged that the only factor considered in their recommendation for adding a 4th program was access, ignoring the importance of cost and quality in Michigan's CON program. You will see in the attached documentation that adding a 4th program comes at considerable financial cost as well as negative impacts on quality, both for patients at the new program as well as potential quality implications at existing programs.

In addition to our concerns with the overall recommendation to add a 4th program and one that can only be placed in Grand Rapids, we believe the Commission would not be acting in-line with the spirit and intent of the Certificate of Need program moving forward language without additional updates to:

- The outdated liver initiation section (Section 5),
- The comparative review criteria (Section 7),
- The project delivery requirements (Section 8), and
- The data projection requirements (Section 9).

We also have concerns with some of the proposed language updates as presented to the Commission. We have provided details on each below.

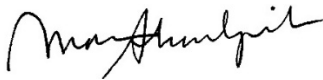
As you will see, the updates needed to these standards are extensive and although we have provided Henry Ford Health's perspective on how these updates should be made, we believe the best approach for moving forward in deciding what specific language should be used is to form a Standards Advisory Committee to continue the work of the previous SAC. These updates are substantive in nature and a broad representation of experts in transplantation should have the opportunity to discuss, debate, and bring forward their recommendations to this Commission before further advancement through the CON process.

We implore the Commission to form a Standard Advisory Committee and charge it to:

1. Recommend necessary changes to the current language in the standards,
2. Consider cost and quality implications of adding a 4th program to the State, and
3. Consider alternative solutions for improving access across the State.

Thank you for this opportunity to share our concerns and potential solutions. We would be happy to participate in any and all future discussions around this issue.

Respectfully,



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Specific Concerns and Recommended Improvements- HLLT Standards

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

The introduction to Section 3 indicates the first transplant must be performed within 18 months of approval. In addition, approved applicants are allowed a single 6-month extension to this deadline under the CON administrative rules, giving an approved applicant a full 2 years to perform even a single transplant. We believe this should be decreased to 12 months with an opportunity for a 6-month extension.

Section 3(1) specifies services and specialties any heart, heart/lung, or liver transplant CON applicant must demonstrate it offers. However, this list is outdated and missing critical components that should be available at a transplant facility. We would recommend adding:

- SURGICAL ICU beds with capacity to take on the forecasted volumes identified in the application for the service, made available whenever an organ becomes available.
- continuous availability of red cells, platelets, and other blood components TO MATCH THE NEED FOR MASSIVE TRANSFUSION PROTOCOL;
- Extracorporeal membrane oxygenation (ECMO)
- Continuous veno-venous hemofiltration (CVVH)
- Transplant anesthesiologist
- Any other requirements called out by Organ Procurement and Transplantation Network (OPTN).

Section 3(5) is a new subsection proposed to be added by the SAC that adds the 4th liver transplant program and requires that program to provide liver transplant services to adults at a minimum. Although this provision is consistent with the SAC's recommendations, it is misplaced. Section 3 is for requirements that apply to all applicants regardless of the type of transplant service being requested. Section 3(5) applies only to applicants applying for a liver transplant service so it should be moved to Section 5.

Section 5. Additional requirements for liver transplantation services

Section 5(3) requires an applicant for a liver transplant program to either already operate a renal transplant service or have a written agreement with an existing renal transplant service located in the same "hospital subarea" that "ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service." This provision is outdated as Michigan's CON program no longer utilizes the term "hospital subarea". Over a decade ago the CON Review Standards for Hospital Beds used to group hospitals into geographic areas called "hospital subareas" but when the hospital bed need methodology was completely re-written more than 10 years ago, that term and practice was removed. Hospitals are now grouped into "hospital groups" which are much smaller than hospital subareas. We propose the agreement be with any existing renal transplant program within the state.

Section 5(4) details the services and programs that a liver transplant applicant must demonstrate they offer as a part of their application; We recommend one clarification to the ICU requirement, to require it be a “SURGICAL intensive care unit with 24-hour per day on-site physician coverage”.

We also believe by not reviewing the provisions in Section 5 at all, the SAC missed an important opportunity to add specific requirements to ensure an approved applicant is truly capable of successfully implementing a new liver transplant program. As such, we would recommend adding the following additional liver transplant initiation requirements:

- In order to ensure the facility is capable of caring for critically ill patients – those that would qualify for a liver transplant, the applicant should have to demonstrate that they have at least 12 Surgical ICU beds, based on approval from the Michigan Department of Licensing and Regulatory Affairs, Health Facilities Engineering Section.
- In order to ensure a new program improves geographic access to as many patients as possible, an applicant should have to demonstrate that the proposed new liver transplant program is located more than 150 aerial miles from the nearest existing liver transplant service.

And before the first procedure is performed, the following should be demonstrated:

- The applicant must have to 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. This is consistent with other CON review standards, including the provisions for providing primary PCI services in the CON Review Standards for Cardiac Catheterization Services.
- The applicants must demonstrate that various policies, procedures, and protocols are in place as outlined by OPTN.

Section 7. Review standards for comparative reviews

Section 7(1)(a) measures applicants against each other based on the percentage of deaths reported to the OPO and MDHHS and allocates almost a third of the total possible points to the applicant with the highest percentage. Though reporting of deaths is important it should not be a primary consideration for which applicant is better situated to start a liver transplant program therefore we would recommend removing this factor from the comparative review criteria.

Section 7(1)(b) allocates points based on the number of existing transplant programs in the planning area but based on what is proposed by the SAC, this criterion would not distinguish at all between applicants. The only purpose of comparative review criteria is to distinguish between applicants so this must be changed. This criterion also accounts for a potential of 4 points or 29% of current possible points. Instead, we would recommend modifying this criterion to instead measure distance to nearest existing transplantation program of the same type being applied for. The applicant with the greatest distance would win the allotted points.

Section 7(1)(c) compares applicants based on indigent care provided at the applicant facility. It references the use of a “DCH-MSA Disproportionate Share Hospital (DSH) report”. "DCH" has historically referred to Department of Community Health which is now MDHHS (Department of Health and Human Services) which is an indication to us that this reference may be outdated. Other standards that have updated their

comparative review criteria no longer reference "indigent volumes" but rather Medicaid volumes. We are concerned that we may be moving forward with language that is outdated and no longer able to be implemented by the Department. We would recommend updating this language to be consistent with other Medicaid participation comparative review criterion in other review standards.

Section 7(1)(d) allocates points based on whether or not the applicant provided pre- and post-transplant care to at least 15 patients in the previous 3 years. With no clear definition of what qualifies as pre- or post-transplant care nor a definition of how close to transplant these services must be provided, any patient who has had a liver transplant that is treated at the hospital, even just an ER visit, could qualify, thus likely resulting in all applicants qualifying for these points. This again, will not provide the distinction between applicants that is needed for the Department to choose which applicant will receive the CON. At a minimum we should better define what qualifies as pre- and post-transplant care. We recommend that the language state the applicant has the capability to perform required pre- and post-transplant testing and follow-up, outlining these capabilities.

In addition to updating the existing comparative review criteria, the Commission should be looking to add criteria to help the Department determine which applicant is best suited to successfully initiate a high-quality program at the lowest cost.

We also recommend awarding points to Applicants in HSAs with the highest average ADI and MELD scores, based on the HSA the applicant hospital is located in.

Section 8. Project delivery requirements – terms of approval

The project delivery requirements contain the rules by which CON holders must implement their project and operate their new service. Making updates to decades old project delivery requirements before a new liver transplant program is approved, is the only opportunity the CON Commission has to ensure a new transplant program is complying with updated guidelines and standards as well as providing outreach to surrounding communities to ensure access is not just improved in the immediate community where the new program is located. We would recommend the following modifications and additions be made to Section 8:

Section 8(2)(a)(i) requires an approved applicant to become Medicare approved within the first 5 years of operations. Until a program is Medicare approved, access to Medicare transplantation is not improved, which is a significant number of transplant patients. Therefore, we would recommend decreasing this deadline to 3 years.

Section 8(2)(b) requires the transplant service to have a transplant "team leader and coordinator". In addition to a transplant team leader and coordinator, these programs should also have a transplant administrator, transplant physician, transplant surgeon, financial coordinator, transplant social worker, a

transplant psychologist, and transplant pharmacist and other roles as identified in the project initiation section.

Section 8(4)(b) requires approved applicants to participate in the CON annual survey and lists specific data that the Department can include in their request. This language is standard in all CON review standards, but this outdated version includes a provision that requires the CON Commission to approve any “other data” requests from the Department that are not specifically listed. The CON Commission has not historically approved Department data requests so this section should likely be updated.

Section 9. Documentation of projections

Section 5 of the standards requires each applicant project at least 12 liver transplants in order to demonstrate need for their proposed program. Section 9 requires each applicant to specify how those volume projections were developed but does not specify how those projections need to be demonstrated. Most other CON review standards spell out very specific requirements for demonstrating projections such as utilizing physician commitments or specific formulas. We believe this section should more specifically define how the liver transplant volume projections should be documented. We strongly urge the Commission to utilize a majority member SAC to determine how these projections should be documented.

HEART LUNG LIVER TRANSPLANTATION SAC

Charge 1: Review liver transplantation access issues based on ***geography*** and ***socioeconomic factors*** and determine if they provide a rationale to increase the number of liver transplant programs. If there is support to expand liver transplantation access, work with the Department to draft edits to the CON Standards to address these access issues.

KEY QUESTIONS TRYING TO ANSWER:

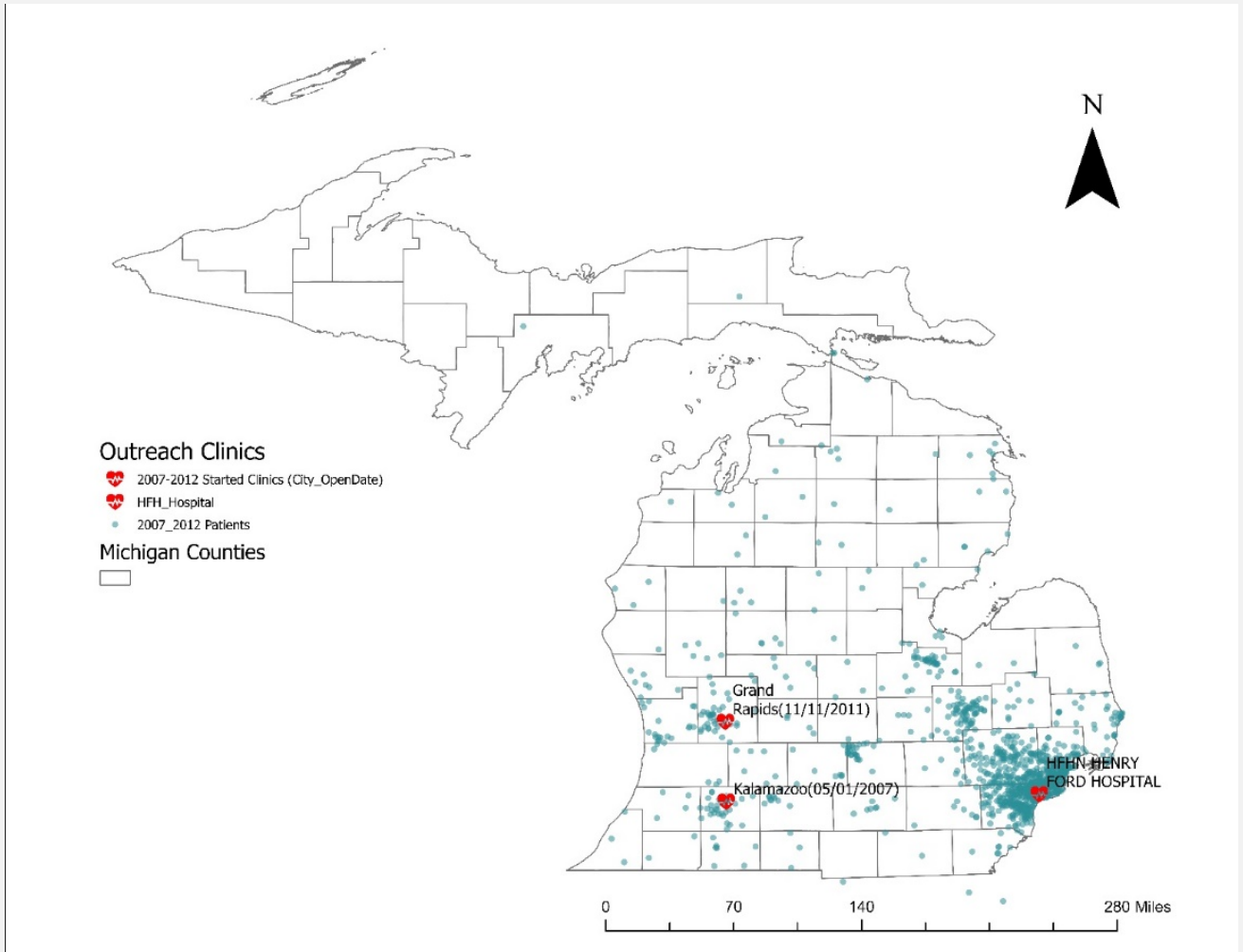
- Does proximity to a Transplant Center *or* to a Transplant Satellite Center improve Outcomes?
- Would putting a Liver transplant program on the West side of the state increase transplantation rates?
- Are there any other factors that would indicate HSA 4 is disadvantaged by not having a Transplant Center?

Questions	Findings	Conclusion
Does proximity to a Transplant Center or to a Transplant Satellite Clinic improve Outcomes?	<p>Research: Satellite liver transplant clinics are associated with significant improvements in waitlisting, transplantation, and pre-transplant mortality.</p> <p>Geographic proximity to these clinics, rather than to the transplant center, conferred a protective effect against pre-LT mortality, suggesting that decentralized care models may mitigate spatial barriers to transplant access.</p>	
Would the additional Liver Transplant Program on the west side of Michigan improve Transplantation rates?	<p>Adding a Transplant program in the Grand Rapids area only creates an improved drive time to transplantation center, but not to a clinic, for a small subset of candidates.</p> <p>If a program were added in SW Michigan, patients on the transplant list will be competing with the highly populated Chicago land area:</p> <ul style="list-style-type: none"> • There would be more available livers for transplantation to compete for • A much larger wait list of candidates • More transplant centers (8 adult programs in Illinois and Wisconsin) • Meaning patients in Southwest Michigan may see longer wait times and be sicker by the time they receive a transplant. 	<p><i>Data shared demonstrate there is not justification for an additional liver transplant. A 4th program only creates added cost to the healthcare enterprise in an area of less need for care.</i></p>
Are there any other factors that would indicate HSA 4 is disadvantaged by not having a Transplant Center?	<p>No; there are no other factors. In fact, patients living in HSA 4 have:</p> <ul style="list-style-type: none"> • The lowest rate of liver related deaths in Michigan • Average MELD score at the time of being put on the Wait List is right at the statewide average of 20 • Average MELD score at time of transplant is also right at the statewide average of 25 • Transplant rate per liver related death is comparable statewide. • Socioeconomic factors do not point to hardship for patients in HSA 4. 	

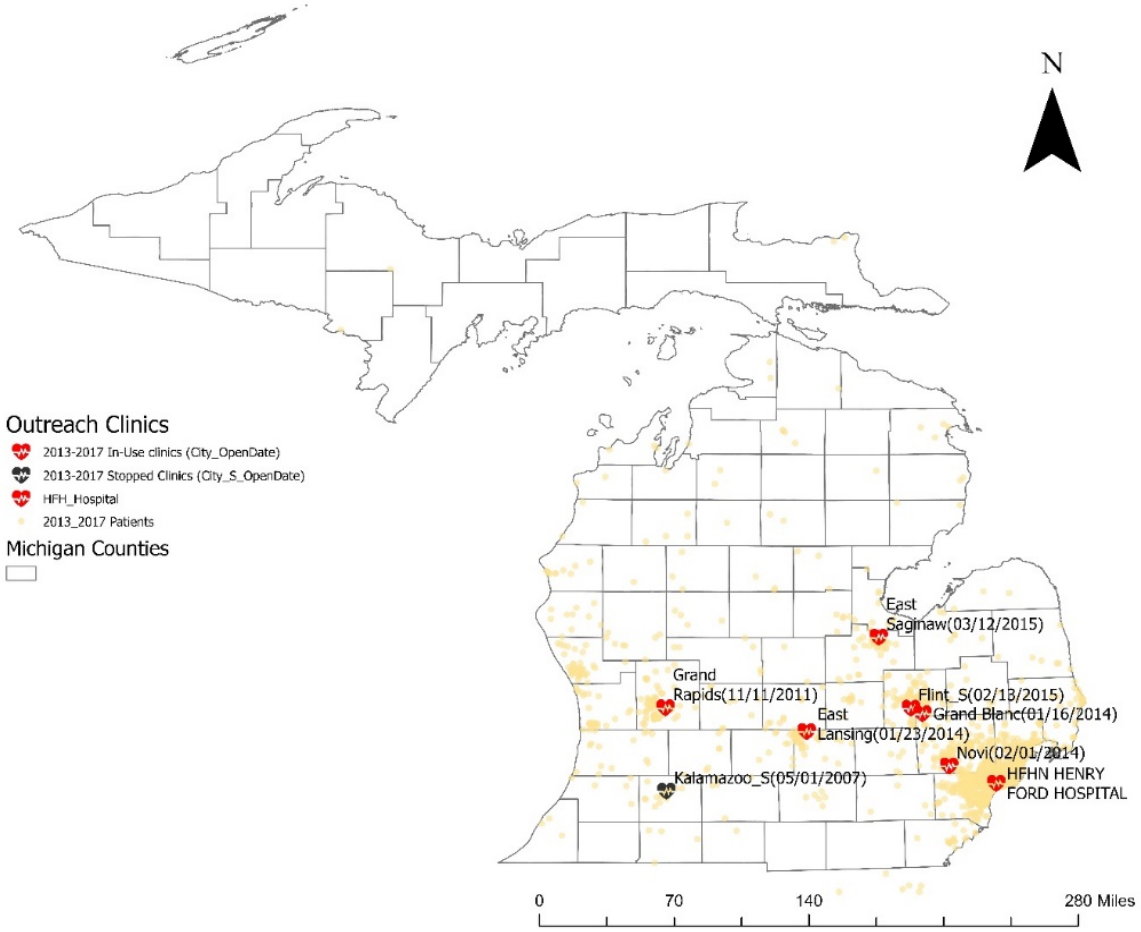
RESEARCH The Implementation of Satellite Liver Transplant Clinics Is Associated with Significant Improvement in Waitlisting, Transplantation, and Pre-Transplant Mortality Over Time, Independent of Disease Severity and Sociodemographic Factors

- **Aim:** To assess the efficacy of Satellite clinics in mitigating the geographical impact on LT evaluation, rates of listing, LT and pre-transplant mortality
- **Methods:** Retrospective study of patients undergoing evaluation for LT during 3 time periods at HFH (2007-12, 2013-17 and 2018-22) to reflect the growing number of Satellite clinics at HFH. Outcomes of WL, LT, Transplant and pre-tpx mortality were assessed at one year following evaluation.
- **Results:**
 - The distance to HF or the nearest clinic decreased over time
 - WL and LT rates significantly increased over time
 - Pre-transplant death rates significantly decreased over time
 - Patient distance from a Satellite clinic did not negatively impact WL or LT rates
 - Patients living closer to Satellite clinics had lower pre-transplant mortality rates
- **Conclusion:** The implementation of Satellite liver transplant clinics was associated with significant improvements in waitlisting, transplantation, and pre-transplant mortality over time. Geographic proximity to these clinics, rather than to the main transplant center, conferred a protective effect against pre-LT mortality, suggesting that decentralized care models may mitigate spatial barriers to transplant access.

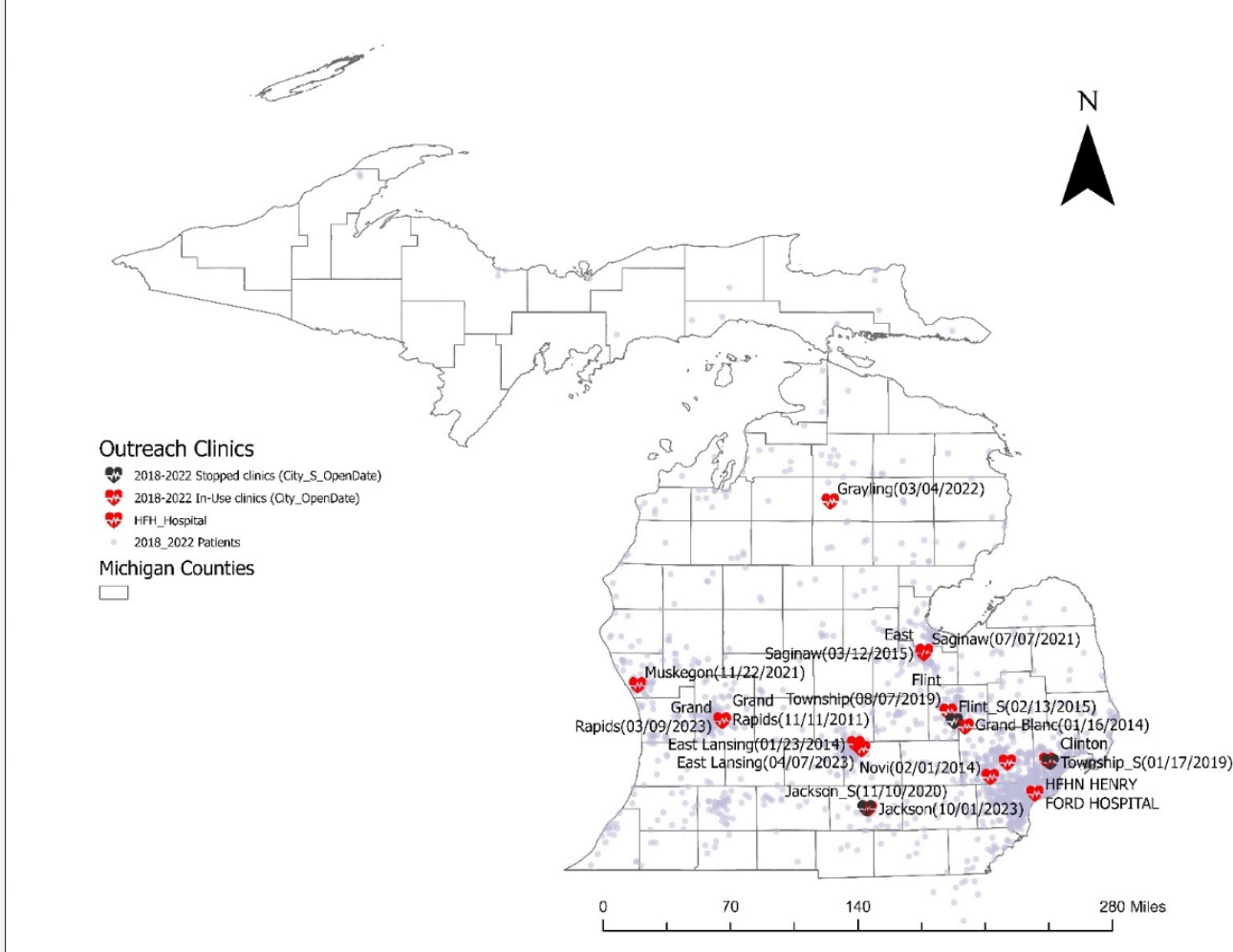
PATIENTS AND SATELLITE CLINICS 2007-2012



PATIENTS AND SATELLITE CLINICS 2013-17

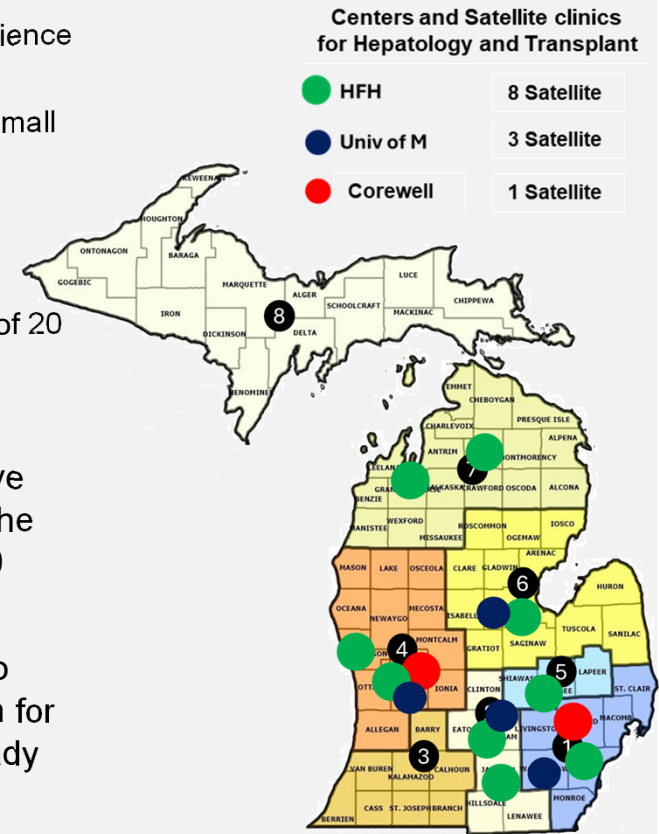


PATIENTS AND SATELLITE CLINICS 2018-2022



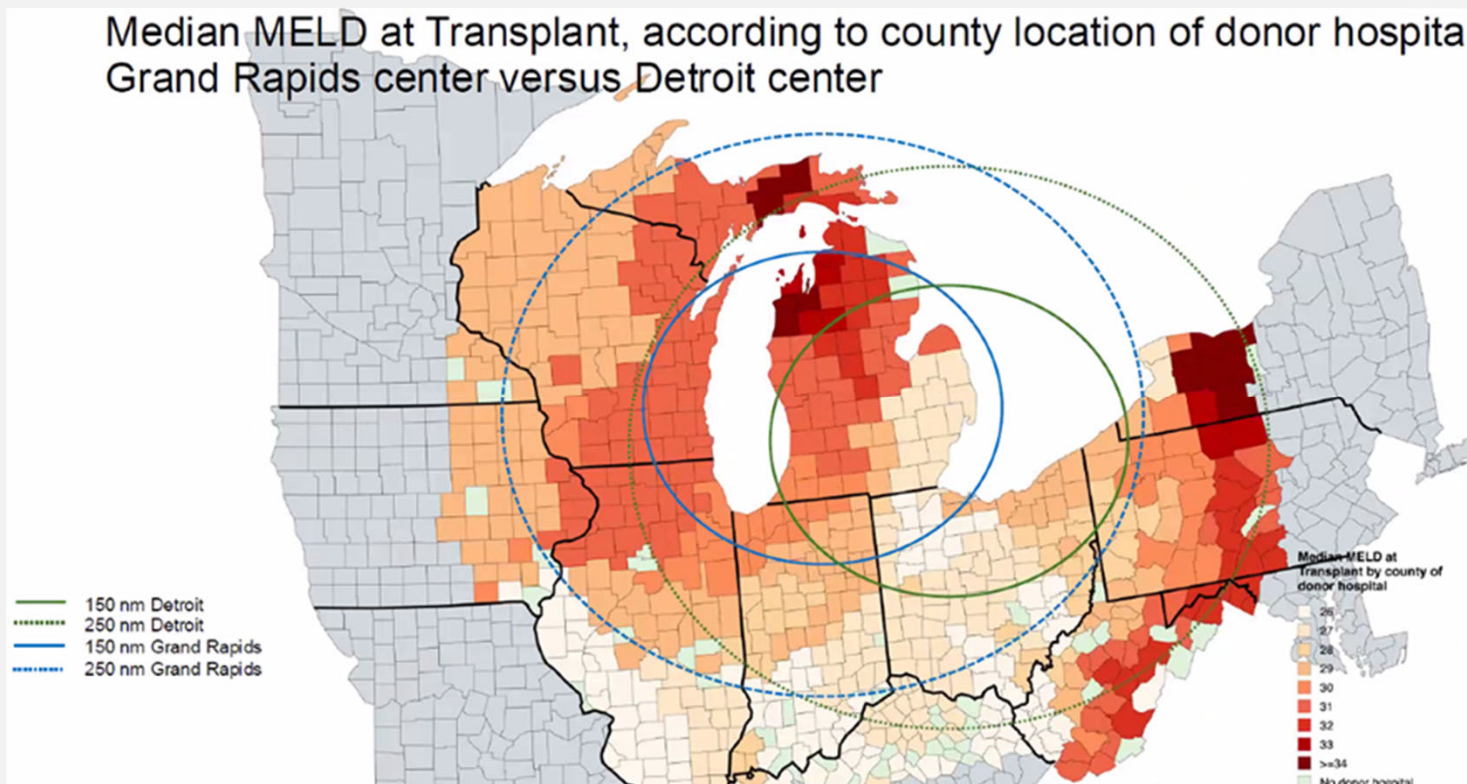
GEOGRAPHY

- Most transplant care happens before and after the actual transplant
 - There are already three hepatology clinics in Grand Rapids, providing local access and convenience to most pre- and post-transplant care.
 - Adding an additional liver transplant program just to reduce the drive time by 60 minutes for a small percentage of patients in region 4 and just for the transplant operation itself.
- The data shows that patients in HSA 4 have excellent access to liver transplant:
 - The lowest rate of liver related deaths in Michigan
 - Average MELD score at the time of being put on the Wait List is right at the statewide average of 20
 - Average MELD score at time of transplant is also right at the statewide average of 25
 - Transplant rate per liver related death is comparable statewide.
- Adding a fourth program, as proposed in the Grand Rapids region, would only improve geographic convenience only for the transplant episode to a small eligible subset of the Michigan population, defined as making a transplant program one hour closer (i.e. 90 minutes rather than 2.5 hours drive time).
- We simply cannot place a liver transplant program in every community in Michigan so geographic convenience for some services alone cannot be a reasonable justification for adding a 4th program. Especially when access to the vast majority of the care is already local.



GEOGRAPHY- If a program were added in Grand Rapids, in aggregate there are more organs, but due to more programs and higher MELD scores in the Chicagoland area, patients in GR will wait longer and be sicker with higher mortality while listed.

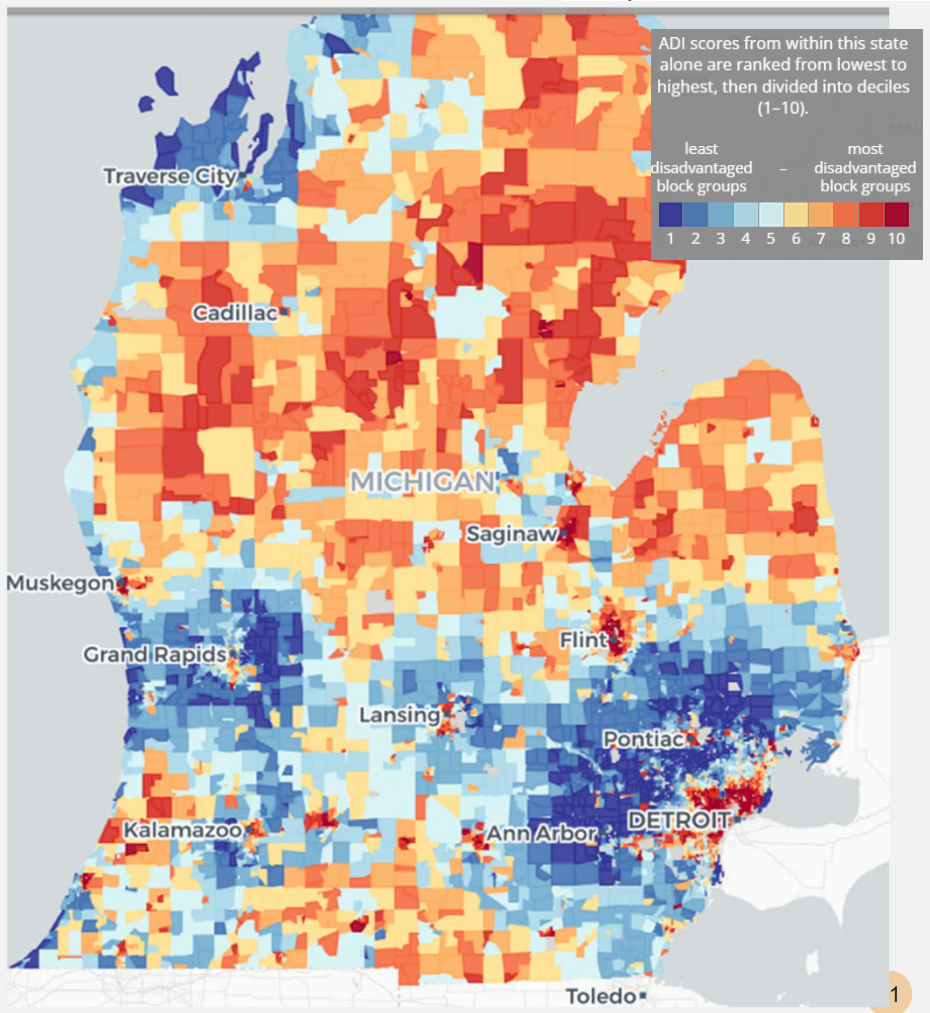
Median MELD at Transplant, according to county location of donor hospital
Grand Rapids center versus Detroit center



- Adding a liver transplant program in Grand Rapids may provide access to a different donor pool than the programs in HSA 1. However, different does not mean better.
 - The data shows that patients in the Chicago market (which is what is being added) have to reach a higher MELD score in order to receive a liver transplant.
- West Michigan patients who are put on the waitlist at a transplant program in SE Michigan have access to donors in Ohio.
 - The data shows patients receive organs at a much lower MELD score, providing better access for patients in Michigan.

SOCIOECONOMIC FACTORS

- The Center for Health Disparities Research Area Deprivation Index (ADI) takes into account income, education, employment, and housing quality in assigning an ADI score to communities with a higher score indicating areas of lower socioeconomic status.
- The ADI score in the Grand Rapids region is much lower than in many other areas of the State, including areas with a much higher rate of liver related deaths, such as the Saginaw/Bay City/Midland areas (HSA 6) and Flint/Lapeer (HSA 5).
- Nothing in the ADI score for HSA 4 would indicate that the population in that area is disproportionately disadvantaged in terms of being able to travel for advanced specialized care such as liver transplantation.
- In fact, patients from all across Michigan choose to travel for transplant to places such as Johns Hopkins, University of Chicago, Mayo Clinic, Cleveland Clinic, and others, even if they have a closer transplant program available.



COST Adding a 4th center will increase costs and are expensive to run and maintain due to Complexity of Care and Regulatory Needs. The expenditures will not result in an increased number of Transplants. While part of the initial charge, this factor was not considered by the SAC.

- Establishing a new liver transplant program is estimated to require substantial financial investment, with costs significantly outweighing the benefits for a limited patient base that already has good access to local liver care and to transplant centers in the State (estimated impact would be approximately 60 transplant candidates living closer to a Transplant Center).
- Costs of starting and operating a liver transplant program with significant steady increases in costs of organ acquisition and preservation continue to rise at a very rapid and prohibitive rate. This has challenged transplant centers and payers especially in the setting of increasing healthcare costs in general with BCBSM posting a loss in 2024 citing increase in medical claims.
- Startup costs can result in \$10 - \$20 million. Program costs include, but are not limited to:
 - Infrastructure of a facility including specialized OR's, ICUs and patient care areas.
 - Medical equipment and facility requirements for advanced imaging, lab, etc.
 - Often this type of program includes research and development
 - Significant reliance on sub-specialized surgeons and specialists (currently a shortage of professionals)
 - Ongoing quality monitoring and regulatory reporting infrastructure
 - Travel for and cost of organ acquisition
- New Programs take several years to ramp-up and are often least aggressive on the types of organs accepted for transplantation.
- Transplant programs must be available 24/7. This is a challenge for large centers, but even more so for smaller programs given the competitiveness for the specialization of physicians and support staff required for these services.

QUALITY

Adding a 4th center will impact quality of care and outcomes, primarily for patients treated at the new center, and potentially at existing programs. While part of the initial charge, this factor was not considered by the SAC.

- Research shows that high-volume transplant centers are associated with improved patient outcomes, including reduced mortality, shorter hospital stays, and lower ICU utilization (<https://pmc.ncbi.nlm.nih.gov/articles/PMC3406353/>).
- Transplant centers achieving scale in volumes of transplant, allow for the building of expertise among teams and ability to perform the most complex procedures while achieving best outcomes. In addition, investments in quality processes and resources are possible due to scale of activity. Consolidation and investment in quality resources is a sound approach to complex care delivery models.
- A new program will undoubtedly be low-volume for many years but could also reduce volumes at existing centers which could compromise quality and resource efficiency statewide.
- A typical pattern for a starting program is to avoid performing transplants on complex patients and those needing multiple organs while avoiding use of extended risk criteria donors. Such scenarios limit care to the local population contrary to the assumption of available all-around access.

DRAFT LANGUAGE

Language to effectuate adding a 4th program was rushed, not considering other key sections in the standards to determine impact of the recommended change and if additional updates are required.

- Only provisions addressed were the definition of planning area to create two planning areas in the state, and language to add a 4th program to planning area 2.
- Sections 5, 7 and 9 were not considered or reviewed:
 - Requirements for initiating a 4th liver program,
 - Project delivery Requirements for operating a 4th program,
 - The comparative review section for determining who should be awarded the 4th program
- The SAC report includes the recommendation to form another SAC to finish the work. Moving the incomplete language forward before the next SAC has the opportunity to recommend updates to Sections 5, 7 and 9 would result in the 4th program being awarded under the outdated provisions, meaning:
 - The wrong applicant could be awarded the CON
 - The awarded program would not have to follow necessary updates to the rules for implementing their program

SUMMARY- Data shared by both subcommittees demonstrate there is not justification for an additional liver transplant. A 4th program only creates added cost to the healthcare enterprise in an area of less need for care.

- In Michigan we have a Certificate of Need, not a Certificate of Want. We simply cannot put a liver transplant program in every community in Michigan and there has been no evidence to support that the Grand Rapids community has a true need for a liver transplant program for access, just a want for improved convenience.
- *Research indicates distance to Satellite clinics is more important in improving outcomes than distance to transplant programs themselves.*
- *Patients in the Grand Rapids area already have convenient access to the vast majority of liver transplant care through Satellite clinics established with that exact purpose in mind.*
- *The cost of adding a 4th liver transplant program to simply improve convenience for the actual liver transplant operation for a small portion of the population is simply unjustified.*
- *Undoubtedly a new program with low volumes will struggle to provide the same quality of transplant as existing programs. In addition, reducing volumes and efficiency of scale and poaching staff from existing programs could negatively impact the quality at the existing programs in the state, increase costs for everyone involved and have an overall detrimental impact to overall services across the State.*
- Patients across the United States must travel for very specialized services like solid organ transplantation – Michigan is not unique. Patients pass by closer transplant centers for many reasons including preferred provider agreements by their insurance carrier, extraordinary medical circumstances, and even simply patient preference.

BASED ON THE FACTS, OUR RECOMMENDATION:

Recommendation 1:

Henry Ford Health encourages the CON Commission to vote to not support a 4th Liver Transplant Program and instead focus on the need to expand hepatology clinics and local pre- and post-transplant services to improve access without compromising existing programs. This includes partnership and education with hepatologists across the state for earlier diagnosis, referral and management of liver disease.

Recommendation 2:

If the Commission does not agree, then we ask that a new Standard Advisory Committee be formed to reconsider this SAC's recommendation, with an emphasis on cost and quality. This SAC should also complete a formal review of all provisions in the standards so more thoughtful revisions can be recommended including initiation, comparative review and project delivery requirements. Any action on the draft language before you should be delayed until the work of this subsequent SAC is completed. This will allow all recommendations to be voted on and implemented at one time.

July 28, 2025

Michigan Certificate of Need (CON) Commission
Michigan Department of Health and Human Services (MDHHS)
333 S Grand Ave
PO Box 30195
Lansing, Michigan 48909

RE: Heart, Lung, and Liver (HLL) Transplantation Review Standards

Dear Commissioners:

Priority Health, a division of Corewell Health, appreciates the opportunity to provide comments on the HLL review standards and whether to open applications for a fourth liver transplantation program in Michigan. With over 30 years of experience, Priority Health is Michigan's second largest health plan, offering an extensive portfolio of health benefits options for employer groups and individuals, including Medicare and Medicaid plans. Offering a broad network of primary care physicians in Michigan, Priority Health continues to be recognized as a leader for quality, customer service, transparency and product innovation.

We are concerned the Standard Advisory Committee (SAC) did not sufficiently weigh cost, quality, and access *together*, despite the explicit requirement to evaluate all three simultaneously—without giving any one criterion undue weight. As a representative on this SAC, I was disappointed by the lack of rigor for the evidence presented, especially for making an informed choice on quality of care and economic burden for Michiganders. Opening a new transplant program will require significant financial investment. For liver transplants, these costs do not proportionately increase quality and access—and in certain circumstances may lower both. For example, a new site competing with the Chicago and Milwaukee markets would mean patients would need to be sicker to get off the new waitlist.

These costs are passed on to employers and patients through higher premiums and taxpayers through higher Medicare and Medicaid spending. The Commission should take more due diligence on all three factors rather than relying so heavily on one system's evaluation when it has its own narrow business case to do so. We believe independent, cost-benefit projections are warranted for a financial investment of this magnitude that would disrupt current market dynamics in coverage, cost, and care.

Liver transplant is a donor-organ limited, highly technical surgical procedure where a fourth program may very easily *lower* quality in multiple ways. While travel time to a transplant center is important, liver transplantation remains a highly specialized surgical procedure. In Michigan and nationally, there is already a limited surgeon and nursing talent pool with enough training and experience to perform liver transplants at high quality standards. The scientific literature consistently shows that higher-volume surgical centers yield better patient outcomes, such as lower mortality rates, shorter hospital stays, and reduced ICU use. Adding a new liver transplant program would likely create a low-volume center, compromising quality outcomes at both the new and existing programs. Instead of creating another costly program, a more effective solution would be to

work with all health care providers and health plans to strengthen and expand satellite clinics, which enhance access without undermining quality or increasing costs. Our state's health care dollar will be better spent spurring the growth of these sites of consistent liver care located in more communities statewide.

Additionally, while we appreciate this opportunity to share our views, it is concerning that an informal open comment will lead to a new Comparative Review when the current standards have not been substantively reviewed in two decades. Having a new SAC update the standards with up-to-date clinical evidence will yield better results for patients and taxpayers. A SAC-mediated update should also bring greater investments and incentives for the myriad local partnerships, social drivers of health, and holistic interventions that bring upstream quality of life improvements. Primary, secondary, and tertiary prevention of liver disease, including chronic disease management, allows more patients to avoid needing a transplant in the first place. Outreach, early intervention, and routine care will save more lives, produce better outcomes, and give patients at risk of liver disease higher quality of life. A new SAC gives all interested parties the chance to give Michiganders modern, clinically meaningful Comparative Review criteria.

For these reasons, we strongly urge the Commission to convene a new SAC to better evaluate cost and quality before moving forward. In addition, no new Comparative Review criteria should be established without the thoughtful, deliberate, open forum that a SAC provides. We believe changes of this magnitude should be decided in a space that is equal to their weight—the divided nature of the prior voting speaks to this need. The decision to emphasize travel time to transplant centers over other measures of access, cost, and quality works against the CON program's core mission. Forging ahead with this recommendation with insufficient data and analysis would risk long-term negative consequences for liver care in Michigan, notably the potential to exacerbate pre-existing disparities among historically marginalized populations.

Thank you for the opportunity to share our comments to ensure that liver transplantation services in Michigan are at high quality standards. Should you have any questions regarding these comments or like additional information, please contact Jon Shiflett, Director, Government Relations, jonathan.shiflett@priorityhealth.com.

Sincerely,

Matthew Blair, D.O.

Medical Director – Medicare
Internal Medicine Board Certified – American Osteopathic Association
Interqual – Certified Expert Reviewer
American College of Physician Advisors - Certified

July 18, 2025

Amy L. Milewski, MD
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Heart, Lung, and Liver (HLL) Transplantation Services

Dear Chairperson Milewski:

Trinity Health would like to thank the CON Commission for its recognition of the need for expanded access to liver transplantation at its June 12, 2025, meeting. We agree with the CON Commission and Standards Advisory Committee findings that a liver transplant program located outside southeast Michigan will address gaps in access to this growing and vital service. We support the language approved at the June 12, 2025, CON Commission meeting, including language regarding the new planning area definitions and improvements to the joint sharing arrangement requirements.

Trinity Health Michigan supports the CON Commission's decision to task the Department to work directly with experts to expedite final improvements to the HLLCON standard. Specifically, we support the Department working with SAC Chair Sonnenday and SAC Vice Chair Bedi to draft changes needed to address the CON Commission's concerns regarding Sections 5, 7, 8 and 9. We are confident these two highly esteemed clinical experts - with their complementary views - are well-positioned to assist the Department in drafting language that best serves the people of Michigan. Further, Trinity Health Michigan would like to contribute the following comments regarding the additional questions posed by the Commission and the Department:

Section 5 (Initiation Requirements). Trinity Health Michigan supports the Department working directly with the experts to determine which services and programs (Section 5(4)) are most relevant for a liver transplant program.

Section 7 (Comparative Review Requirements). As has been done in other review standards with comparative review requirements, Trinity Health Michigan supports updating the existing requirements to ensure the scoring sufficiently differentiates between applicants, and results in approval of the qualified applicant. Any new metric should be based on data from publicly available sources or the applicant facility's own data, which can be provided to MDHHS for purposes of comparative review.

- As in other review standards, Trinity Health Michigan supports heavily weighing Medicaid participation as a comparative review requirement. Trinity Health Michigan recommends replacing the outdated language in Section 7(1)(c) with language modeled from the Psychiatric Beds Standard, using the Medicaid cost report associated with an applicant hospital's NPI.
- Trinity Health Michigan supports adding quality metrics to the comparative review standards. Options may include the CMS Star Ratings, as is used in the Hospital Beds Standards, and/or the Scientific Registry of Transplant Recipients (SRTR) Find and Compare Programs reports for kidney

transplantation. SRTR may be most relevant to the HLL Standards because applicants seeking to add liver transplantation services must already provide kidney transplantation services.

Section 8 (Project Delivery Requirements)

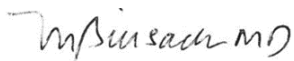
Trinity Health Michigan supports the Department working directly with the experts to determine which quality assurance and access to care metrics are most relevant for a liver transplant program.

Section 9 (Documentation of projections)

Trinity Health Michigan supports the Department working directly with the experts to determine if a specific methodology is required for the projection of volumes for a facility that does not currently offer the service. Any new methodology should be designed to ensure the data are from publicly available sources or the applicant facility's own data. Applicants should not be expected to provide data they do not own or that is not publicly available, such as private physician data.

We appreciate the CON Commission's consideration of our comments and look forward to the Commission and Department advancing changes in the Heart, Lung and Liver Transplantation CON standard in an expedited manner.

Sincerely,



Matthew P. Biersack, MD
President, Trinity Health Grand Rapids

July 23, 2025

Amy L. Milewski, MD - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Heart, Lung and Liver Transplantation SAC Recommendations

Dear Chairperson Milewski:

On June 12, 2025, the CON Commission took proposed action based on the recommendations of the Standards Advisory Committee (SAC) for Heart, Lung and Liver Transplantation. Specifically, the SAC recommended that a fourth adult liver transplant program is needed outside Southeast Michigan. The proposed rationale was to improve access to transplant care for patients residing distant from Southeast Michigan where other programs are located. Michigan Medicine supports this recommendation as it is based on an objective assessment of the need to improve geographic access to liver transplant programs for Michiganders.:

- Michigan ranked 25th in 2023 for age-related death rates for Liver Disease.
- Michigan is average in efforts to address liver disease mortality, with minimal progress relative to other states in recent years.
- Michigan compares unfavorably nationally and to neighboring states in liver-related deaths, the number of transplant centers per capita, and the number of transplants per capita.
- Only Southeast Michigan (Planning Area 1) seems to be performing relatively well: data indicates that people in many counties outside southeast Michigan have more disease burden and disproportionately lower transplant rates.
- Research indicates that distance to a transplant center may contribute to a lack of access and lack of progress in reducing liver disease mortality; the data indicates that some Michiganders are traveling for care, but many others are not. Public insurance and lower socio-economic status also impact access when long distances are involved.
- Nearly 3 million Michiganders live more than 100 miles from a Michigan liver transplant center, a number will likely increase as Michigan's population continues to grow in western and northern lower Michigan.
- A liver transplant center in West Michigan would mean nearly 2 million additional Michiganders would gain improved access to a liver transplant center that is within 100 miles of their homes, reducing substantive barriers and providing equitable access to life-saving care to a growing population.
- A liver transplant center in West Michigan would have better access to organs in Illinois and Wisconsin that are currently less available to the centers in Southeast Michigan.

Michigan Medicine operates one of the three existing liver transplant centers in Michigan and believes, based on these findings, adding a fourth liver transplant program outside Southeast Michigan will benefit the citizens of Michigan. Improving geographic access to this quaternary program will help many additional Michiganders who would otherwise have significant challenges accessing this lifesaving surgical procedure located a great distance from home.

Due to time constraints, the SAC did not have the opportunity to thoroughly review and provide recommendations for Sections 5, 7, 8, and 9 within the CON Standards for Heart, Lung and Liver Transplantation. Based on the proposed changes received during this public hearing, Michigan Medicine supports continued expert review and analysis for future CON Commission review and decision.

Thank you for your attention and the opportunity to provide these comments for consideration.

Respectfully submitted,



David C. Miller, MD, MPH
Executive Vice President for Medical Affairs &
Chief Executive Officer
Michigan Medicine



T. Anthony Denton, JD, MHSA
Senior Vice-President &
Chief ESG Officer
University of Michigan Health
Michigan Medicine