

**Michigan Department of Community Health (MDCH) Comments and
Recommendations
for Certificate of Need (CON) Review Standards
Scheduled for 2009 Review
Presented to CON Commission February 5, 2009**

PANCREAS TRANSPLANTATION SERVICES (Please refer to MDCH staff summary of comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of pancreas transplants under CON.	Yes	Workgroup to bring back information for Commission consideration.	The information should include discussions regarding any relationship between pancreatic and kidney transplantation.
2. Remove the volume requirement for pancreas transplants.	Yes	Workgroup to bring back information for Commission consideration.	According to the Federal Register (Vol. 72, No. 61), there is no annual volume requirement for pancreas transplants.
3. Make technical changes and updates that provide uniformity in all CON standards, i.e., revisions to reference of online system.	Yes	MDCH to draft recommended language.	
<p>Recommendation: MDCH recommends a workgroup be formed to provide information for the Commission. The information should present pros/cons and describe the impact for items #1 and #2.</p> <p>The Department recommends that the Commission assign the responsibility to draft any necessary technical language changes to the standards to the Department. Language changes for these standards should all be moved forward to public hearing simultaneously.</p>			

PANCREAS TRANSPLANTATION SERVICES

Summary of 10/16/08 Public Hearing Comments and Department Comments

Prepared by: MDCH

Considerations from 10/16/08 Public Hearing.

Public Hearing Summary: The complete oral and written testimonies are included in the February 5, 2009 CON Commission meeting binders. The agencies represented were as follows:

- Economic Alliance of Michigan (Verbal and Written): Believes there is no reason for the standards to be opened up for review at this time. Additionally, they urge the Commission to not further loosen the requirements.
- Blue Cross Blue Shield (Verbal and Written): Believes there is no reason to review these standards as a state-wide review of pancreas transplant data shows relatively consistent volumes for these services. Additionally, states that because of low patient volumes that Harper and St. Johns hospital voluntarily surrendered their CONs for this service.
- St. John Hospital and Medical Center (Verbal and Written): In 2007, St. John voluntarily surrendered their CON for pancreas transplants based on the fact that they were reaching lower than expected volumes for these services. They would like their certificate reinstated and have provided reasons as to why it should be. First, they state that quality of care must be the most important concern of the Commission. There have been data posted by the Scientific Registry of Transplant Recipients which shows that larger center volume does not improve the outcome as it does in other procedures. The pancreas graft is a very fragile organ, and if they attempted to increase their volume figures, then they would be utilizing more marginal organs which greatly reduce both the graft and patient survival. Secondly, they state that cost issues should not be of concern as when you have a busy kidney transplant program it costs nothing to add pancreas on. Thirdly, St. John feels that the largest issue to be addressed by the Commission is access to care. With centers having to shut down operations due to not meeting volume requirement, it is causing patients to have to travel further away for procedures and follow-up

Policy Issues to be Addressed

Recommendations to consider:

1. The following items should be explored:
 - Two transplant centers (St. John & Harper) have had to voluntarily surrender their CON for pancreas transplants as they were unable to meet the volume of 12 per year.
 - According to the Federal Register (Vol. 72, No. 61), there is no annual volume requirement for pancreas transplants.
 - In 2007, only one, University of Michigan, of the four pancreas transplant centers met the volume requirement. Of these four centers, two have now surrendered their CON. This only leaves two pancreas transplant centers (University of Michigan and Henry Ford). Please see attached chart.
 - The number of these types of transplants performed at the centers has remained relatively stable over the last seven years (2000 to 2007). There haven't been any significant increases or decreases.
 - The limited number of specialized staff is already a concern for existing programs. There have been no scientific bases identified upon which to base an appropriate number.
 - Kidney transplants are not regulated by CON. Considering that pancreatic transplants may be an adjunct to kidney transplants, differentiating between the two does not make sense.

care.

- Harper University (Ms. Andrea Spraggins) (Verbal): Works for Harper as a social worker on the transplant team and also a transplant recipient of both a kidney and a pancreas after kidney. She was the one transplant recipient in 2005 for Harper and had the CON been pulled she would not be here to share her story. She believes there should not be a volume criteria on the number of transplants performed each year. Now that Harper has given up their CON for pancreas transplants, her patients have to travel to U of M for treatment which causes many issues for these patients. First, the majority of the patients are Medicare and Medicaid, and they do not have the financial strength to be able to travel to other transplant centers located many miles from them. Ms. Spraggins states that transportation is a major need for these patients.
- University of Michigan (Written): Does not oppose the modification of the pancreas transplant standard to reflect a lower volume requirement. They recognize that Gift of Life Michigan is under a federal mandate to maximize pancreas utilization in its service area. However, if a lower volume requirement is made, they believe that the existing quantitative kidney transplant volume prerequisite for approval of a pancreas transplant program remain the same.
- Gift of Life Michigan & Harper University (Dr. Scott Gruber) (Verbal & Written): There is no correlation between the number of transplants performed and their outcomes. Dr. Gruber states that the outcome of lower-volume programs in the state, in particular the two that have voluntarily surrendered their CON, are as good as those of higher-volume programs. Also, states that the pancreas is a no-cost add-on over and above that of performing kidney transplants. No additional equipment is needed or additional capital to start a program. Additionally, no extra personnel are needed as the same team of professionals is used for pancreas transplant patients as that of kidney transplant patients. Having a volume requirement causes patients whom have had all of their care at one hospital, such as Harper, have to transfer to another hospital or be unable to obtain the transplant at all. These patients may not have insurance coverage allowing them to go elsewhere, and additionally, the patients do not want to transfer to a brand new center and start all over again with becoming comfortable

<p>with the medical staff. Lastly, Dr. Gruber states that there isn't any rational basis for continuing the volume criteria as part of the CON for pancreatic transplantation in Michigan beyond that which already exists at the federal level. **Note: his written testimony includes a copy of his PowerPoint presentation; this includes a couple of data tables that he put together.</p> <ul style="list-style-type: none"> • Gift of Life Michigan (Mr. Richard Pietroski) (Verbal and Written): The current CON volume requirement impacts patients, transplant centers, and Gift of Life Michigan. They suggest that the standards be revised to the following: 1) A hospital will qualify to provide pancreas transplant services through the establishment of an on-site renal transplant service that has performed a minimum of 80 kidney transplants in any 24 consecutive months in the most recent three years for which data are available. 2) A hospital will be considered to be active by performing at least one pancreas transplant in a six month period; otherwise, the center must submit any required federal OPTN center status review documents for examination and center certificate disposition by the CON Commission. The current standards impact Gift of Life in that they are expected to maintain a certain number of organs transplanted per donor. If they fall more than one standard deviation below the national mean, Gift of Life Michigan would be decertified. The potential for this happening is great if Michigan doesn't have sufficient transplant centers in operation such as that of one or two. This causes the patient population to be underserved and therefore poses a threat to Gift of Life. They note that if they become decertified then organ recoveries would have to be performed by one of Michigan's neighboring states. Additionally, they have attached data tables as well as their PowerPoint presentation. 	
<p>1. Review current standards for the volume requirement for the number of pancreas transplants to be preformed annually Note: Consideration from 10/16/08 Public Hearing.</p>	
<p>Current Standards</p> <p>Section 3. Requirements for approval -- all applicants</p> <p>(3) An applicant for a pancreas transplantation service shall project a minimum of 12 pancreas transplantation procedures annually in the second 12 months</p>	

<p>of operation following the date on which the first pancreas transplant procedure is performed and annually thereafter.</p>	
<p>2. . Review current projection requirements. Note: Consideration from 10/16/08 Public Hearing.</p>	
<p>Current Standards</p> <p>Section 5. Documentation of projections</p> <p>Sec. 5. An applicant required to project volumes of service under Section 3 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.</p>	