



**MARYLAND HEALTH CARE COMMISSION**

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**MEMORANDUM**

**TO:** Commissioners

**FROM:** Eileen Fleck *E.F.*  
Chief, Acute Care Policy and Planning

**DATE:** September 20, 2016

**RE:** Staff Recommendation for Proposed Permanent Regulations: State Health Plan for Facilities and Services: Organ Transplant Services (COMAR 10.24.15)

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations a replacement COMAR 10.24.15: State Health Plan Chapter for Facilities and Services: Organ Transplant Services (“Chapter”). A draft Chapter was posted for informal public comment on May 5, 2016 and two organizations commented on this draft Chapter. MHCC staff provided analysis and recommendations regarding the comments received to the MHCC at the meeting held on July 21, 2016. MHCC staff were asked at this meeting to convene the organ transplant work group to discuss issues raised by MHCC at this meeting. These issues included whether the draft Chapter could be revised further to address the disparity between the demand and supply of organs, whether the docketing rules potentially shut out programs that could reduce the disparity between the demand and supply of organs, and whether the threshold volume standards are appropriate for determining when to allow consideration of new transplant programs. The work group recommended no additional changes to the draft Chapter to address these issues.

With regard to the disparity between supply and demand, the work group concluded that other organizations can better address the issue, and one work group member described a national initiative that may increase the number of kidney transplants through reducing the number of kidneys discarded. By changing the federal performance metrics used to evaluate kidney programs, it is expected that some transplant surgeons will become less risk adverse and more willing to transplant kidneys of lower quality. If the initiative is successful, it could be regarded as having effectively increased the supply of organs, allowing for more organ transplants. The use of lower quality kidneys is likely to also increase the number of unsuccessful transplants, and that is why changes to the federal performance metrics have been proposed. In addition to the national initiative for kidneys, which would be a pilot project for a limited number of programs, changes to the federal performance metrics used across multiple

types of organ transplants have been proposed that, similarly, are intended to reduce the number of discarded organs by reducing surgeons' risk aversion to transplanting lower quality organs.

Work group members, including those who do not represent an existing transplant program, concluded that the docketing rules are acceptable and did not share the concerns raised by Commissioners about shutting out applicants and negatively affecting patients' access to transplant services. Work group members noted the cost-effectiveness of expanding existing programs rather than setting up a new program. There were no proposed changes to the threshold volume standards referenced in the docketing rules. However, it was proposed that the title of the table with the threshold volume standards be revised to better align with the text of the docketing rule, which references the average annual volume over three years, rather than the annual volume. MHCC staff made changes on two pages of the draft Chapter in response to this comment. These pages have been attached as Appendix 1, with new text underlined and deleted text shown with strikethroughs.

## **Appendix 1**

**.04 Certificate of Need Docketing Rules**

A. The Commission shall only docket an application to establish a new organ transplant service if all existing non-federal organ transplant programs of the same organ type in the health planning region have been in operation for at least three years and achieving at least the applicable three-year average annual threshold case volume, based on the most recent data available through UNOS no more than 45 days ~~on average for the three years~~ prior to the filing of the application, except that the following shall not be included in such a determination:

(1) An organ transplant service in the health planning region that has been designated by the Organ Transplant and Procurement Network as a member not in good standing; or

(2) An organ transplant service located outside of Maryland but within the health planning region fails to meet and maintain minimum volume requirements that would apply to a similarly situated organ transplant service in Maryland such that the service for the same type of organ would be considered for closure by the Commission if it were located in Maryland.

B. The Commission may docket an application to establish a new organ transplant service in Maryland if a CON process to establish the same type of organ transplant service has been initiated or completed outside of Maryland but within the health planning region, if a letter of intent to establish a transplant service in the planning region has been filed with the Commission prior to the completion of the CON process outside of Maryland.

**Table 2: Three-Year Average Annual  
Threshold Case Volume Requirements by Type of Organ**

Type of Organ	Annual-Threshold Case Volume Requirement
Kidney Adult Pediatric	50 10
Liver	20
Pancreas /Heart Lung	No requirement
Heart	20
Lung	20
Hematopoietic Stem Cell: Autologous Allogeneic	10 40
Intestine/Small Bowel, Islet Cells, Hepatocytes.	No requirement
Vascular Composite Allograft	No requirement