STATE OF MARYLAND

Craig P. Tanio, M.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

DRAFT FOR INFORMAL PUBLIC COMMENT

STATE HEALTH PLAN FOR FACILITIES AND SERVICES:

ORGAN TRANSPLANT SERVICES

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Send to: Eileen Fleck
Chief, Acute Care Policy &Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215
Email: Eileen.fleck@maryland.gov
Fax: (410) 358-1236

TABLE OF CONTENTS

Page

State Health Plan for Facilities and Services: Specialized Health Care Services – Organ Transplant Services

.01 Incorporation by Reference.

This chapter of the State Health Plan for Facilities and Services: Organ Transplant Services (Chapter) is incorporated by reference in the Code of Maryland Regulations.

.02 Introduction.

A. Purposes of the State Health Plan.

The Maryland Health Care Commission (the Commission) has prepared this Chapter of the State Health Plan for Facilities and Services (State Health Plan) in order to meet current and future health care system needs of all Maryland residents by assuring access, quality, and cost-efficiency.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources; and

(2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in services for health care facilities are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, standards and service-specific need projection methodologies that the Commission uses in making decisions on applications for Certificate of Need (CON), Certificates of Conformance, and Certificates of Ongoing Performance.

B. Legal Authority of the State Health Plan.

The State Health Plan is adopted under Maryland's health planning law, Maryland Code Annotated, Health-General (Health-General) §19-114 - 19-131. This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the State Health Plan as necessary. Health-General §19-118(a)(2), provides that the State Health Plan shall include:

(1) The methodologies, standards, and criteria for CON review; and

(2) Priority for conversion of acute capacity to alternative uses where appropriate.

C. Organizational Setting of the Commission.

The Commission is an independent regulatory agency functioning administratively within the Department of Health and Mental Hygiene (DHMH) whose mission includes planning for health system needs. The purposes of the Commission, as provided in §19-103(c), include:

(1) Development of health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission;

(2) Promotion of the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system;

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificates of Need, Certificates of Conformance, Certificates of Ongoing Performance and exemptions based on the State Health Plan. Health General §19-118(e) provides that the Secretary of the DHMH shall make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. Health-General §19-110(a), however, clarifies that the Secretary does not have the power to disapprove or modify any determinations the Commission makes regarding or based upon the State Health Plan. The Commission pursues effective coordination of its health planning functions with the Secretary, with State health-related agencies, and with the Health Services Cost Review Commission in order to assure an integrated, effective health care policy for the State. The Commission also consults the Maryland Insurance Administration as appropriate.

D. Plan Content and Applicability.

This Chapter specifies requirements to obtain a CON for the establishment of new solid organ and transplantable cell programs. Under §19-120(j)(2)(iii)2 of the Health-General Article, Annotated Code of Maryland, and COMAR 10.24.01.02(4)(b), a CON is required for the establishment of organ transplant surgery. A separate CON is required for the development of a new transplant program in each of the categories listed in Table 1 below, whether or not the institution has another type of organ transplant program. The ability to provide one type of organ transplant does not enable a hospital to perform any other type of organ transplant because surgical specialization and post-surgical management of patients are unique for each organ transplant type. In addition, a merged hospital system may not relocate any part of any existing organ transplant program to another hospital within its system without obtaining a CON.

Table 1. Categories of Covered Transplant Programs

Solid Organ Programs	Kidney Liver Pancreas Heart Lung Heart/Lung Intestine (Small Bowel) Others, to be determined by the Commission as needed
Hematopoietic Stem Cell (Bone Marrow) Programs	Autologous Allogeneic
Other Transplantable Cells	Islet Cells Hepatocytes Others, to be determined by the Commission as needed
Other	Vascular Allograft

.03 Issues and Policies.

Organ transplantation is the process of surgically transferring a donated organ into a patient with end stage organ failure. It also includes the transfer of a vascularized human body part containing multiple tissue types (skin, muscle, bone, nerves, and blood vessels) as an anatomical or structural unit from a human donor to a human recipient, when such a transfer is susceptible to allograft rejection that generally requires immunosuppression for the recipient, and other specified criteria are met.[1] Organ transplantation is often the only treatment for the end stage failure of certain organs such as the liver and heart, and it is the most cost effective treatment for the management of other organ failure such as kidney failure which is otherwise managed with peritoneal dialysis or hemodialysis.[2] Transplants are provided to segments of the population that are the most severely ill and at the highest risk for poor outcomes. For purposes of regulation under this Chapter, organ transplantation refers to the major solid organs (kidney, liver, pancreas, heart and lung), intestine or small bowel, hematopoietic stem cells, vascular composite allografts (VCAs) and other transplantable cells.

Regulation of Organ Transplantation

The National Organ Transplant Act (NOTA) of 1984 provided for the establishment of the national Organ Procurement and Transplantation Network (OPTN) in response to the growing need for donor organs and for a more centralized and national organ donation registry. Before this law was passed, hospitals and regional hospital collaborations relied on a supply of donor organs within their own networks for their own patients in need. The OPTN links all of the professionals involved in the donation and transplantation system.[3] The primary goals of the OPTN are to: increase organ sharing effectiveness and efficiency and improve equity in organ allocation. While OPTN is responsible for developing transplantation policy, the

[1] 42 CFR §121.2

[2] Abecassis, M., Bartlett, S.T., Collins, A.J., Davis, C.L., Delmonico, F.L., Friedewald, J.J., Hays, R., Howard, A., Jones, E., Leichtman, A.B., Merion, R.M., Metzger, R.A., Pradel, F., Schweitzer, E.J., Velez, R.L., Gaston, R.S. Kidney Transplantation as Primary Therapy for End-Stage Renal Failure: A National Kidney Foundation/Kidney Disease Outcome Quality Initiative Conference, *Clinical Journal of American Society of Nephrol*ogy. 2008 March; 3(2): 471-480.

[3] Organ Procurement and Transplantation Network. "Governance." http://optn.transplant.hrsa.gov/. Accessed May 4, 2016.

Scientific Registry of Transplant Recipients (SRTR) also plays a role by providing ongoing evaluation and data analysis necessary for policy makers to make informed decisions.

NOTA required the OPTN network to be operated by a private non-profit organization under a federal contract.[4] The Department of Health and Human Services (HHS) awarded the OPTN contract to the United Network for Organ Sharing (UNOS) in 1986.[5] UNOS develops, monitors, and enforces the rules governing allocation, procurement, and transplantation of all organs (not including bone marrow transplants), as approved by HHS. UNOS manages the waiting list for transplants in the U.S. and matches donors to recipients.[6] One of the goals of UNOS is to increase the number of organs available for transplantation and to maximize the efficient use of available organs through equitable and timely allocation. In order to efficiently and equitably distribute organs to those who need a transplant, UNOS's board of directors approved criteria based on medical and logistical factors and incorporated the criteria in a computer matching system that generates a rank-order list of candidates to be offered each organ.[7] The candidates with the highest ranking are those who most urgently need a transplant and who have the best chance of survival following a transplant.[8]

UNOS divides the U.S. into 11 regions.[9] This regional system provides a mechanism for communication between UNOS and the transplant community and provides a forum for consensus building. Maryland falls within Region 2, which also includes Delaware, the District of Columbia (D.C.), New Jersey, Pennsylvania, West Virginia, and Northern Virginia. Within regions, Organ Procurement Organizations (OPOs) are designated by the Centers for Medicare & Medicaid Services (CMS) to facilitate organ procurement and transplantation at the local level, with only one OPO designated to each Donation Service Area (DSA).[10] OPOs are required to meet certain standards for process and outcome measures. Outcome measures include the donation rate of eligible deaths, the number of organs transplanted per standard criteria donor,

[4] 42 USC §273
[5] Organ Procurement and Transplantation Network. "History & NOTA." https://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/. Accessed January 25, 2016.
[6] United Network for Organ Sharing. "How organs are matched." https://www.unos.org/transplantation/matching-organs/. Accessed May 4, 2016.
[7] Ibid.
[8] Ibid.
[9] Ibid.
[10] 42 CFR §486.308

the number of organs transplanted per expanded criteria donor, and the number of organs used for research per donor.[11] The process measures include participation in the organ procurement and transplantation network, data reporting requirements, organ transport preparation and transport requirements, and implementation of a quality assessment and performance improvement program.[12]

Currently, two OPOs provide organ procurement and distribution services to Maryland jurisdictions. The Washington Regional Transplant Community (WRTC) is the OPO serving the District of Columbia, Montgomery, Prince George's and Charles Counties in Maryland, and Arlington, Clarke, Fairfax, Fauquier, Loudoun, King George, Prince William, Spotsylvania, and Stafford Counties located in northern Virginia, as well as the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park in Virginia. The Living Legacy Foundation in Maryland (LLC) is the OPO serving western and central Maryland, the Eastern Shore, Calvert, and St. Mary's counties in southern Maryland. The health planning regions for CON review of an application to establish or relocate organ transplant services in Maryland shall be consistent with the OPO designations. For purposes of this chapter, the health planning regions will change, as needed, to reflect any changes in the designated service areas of the OPOs.

Specialized Health Care Service

Transplantation is a specialized tertiary-level health service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment. Deceased donors provide kidneys, pancreas, liver, lungs, heart, intestines, and bone marrow. Living donors can provide a kidney, bone marrow, or a portion of the liver, lung, or intestine.[13] In 2014, 68 percent of the kidneys transplanted came from deceased donors and 32 percent from living donors.[14] Kidney transplants decreased by about nine percent between

[11] 42 CFR §486.318
[12] 42 CFR §486.320-486.348
[13] U.S. Department of Health and Human Services. "Organ and Tissue Donation from Living Donors." http://www.organdonor.gov/about/livedonation.html. Accessed May 4, 2016.
[14] National Kidney Foundation. "Organ Donation and Transplantation Statistics." https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats. Accessed May 4, 2016.

2012 and 2014, from 18,783[15] to 17,107.[16]

For specialized services, the public is best served if a limited number of hospitals provide specialized services to a substantial population base. This pattern promotes high quality care and an efficient scale of operation. As discussed later, higher volume transplant programs are often associated with better patient outcomes. To gain these benefits, a large population base is necessary to ensure that programs have adequate caseloads.

Cost Effectiveness

Tertiary care interventions tend to occur late in the disease process. Since these interventions are provided to segments of the population that are the most severely ill and at the highest risk for poor outcomes, the diagnostic and therapeutic services are more advanced, and the cost of staffing and equipping these specialized health care services is very high. Transplantation is often considered to be the most cost-effective treatment for the failure of certain organs. Although the initial cost of the kidney transplant and hospitalization is likely very high based on estimated average billed charges in 2014 of $140,100[17] compared to the estimated cost for Medicare beneficiaries receiving hemodialysis ($84,550 per year in 2013),[18] the cost per year for care following transplantation decreases significantly. The average annual cost for Medicare beneficiaries who had previously received a kidney transplant was $29,920 in 2013, which is much less than the reported average annual cost for Medicare beneficiaries who received dialysis in 2013 ($69,919).[19] In addition, many individuals who receive a kidney transplant have an improved survival rate and a better quality of life than individuals on hemodialysis.[20]

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[15] Scientific Registry of Transplant Recipients. "OPTN/SRTR 2012 Annual Data Report: kidney." http://srtr.transplant.hrsa.gov/annual_reports/2012/pdf/01_kidney_13.pdf. Accessed May 4, 2016.
[16] National Kidney Foundation. "Organ Donation and Transplantation Statistics." https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats. Accessed May 4, 2016.
[17] Milliman Research Report. "U.S. organ and tissue transplant cost estimates and discussion." December 2014. http://www.milliman.com/uploadedFiles/insight/Research/health-rr/1938HDP_20141230.pdf. Accessed May 4, 2016.
[18] United States Renal Data System. "Chapter 11: Medicare Expenditures for Persons With ESRD." http://www.usrds.org/2015/view/v2_11.aspx. Accessed May 4, 2016.
[19] Ibid.
[20] Berns, J.S. "Patient information: Dialysis or kidney transplantation -which is right for me?" http://www.uptodate.com/contents/dialysis-or-kidney-transplantation-which-is-right-for-me-beyond-the-basics. Accessed May 4, 2016.

Organ failure, leading to the need for organ transplantation, often is the result of preventable disease and lifestyle behaviors.[21] When addressed early in a disease process, risk factors can often be reduced, and organ failure can sometimes be slowed or halted. Education efforts should focus on prevention, early detection, and treatment of diseases and conditions such as diabetes, coronary artery disease, alcohol and substance abuse, and hypertension that may lead to end stage organ failure.[22] Education efforts should also focus on increasing the number of potential organ donors, particularly living donors. The outcomes of living donor transplants have been reported to be better than the outcomes of deceased-donor transplants due to improved graft survival rates and a reduction in acute rejection rates.[23]

Quality of Care

CMS regulations for participation in the Medicare and Medicaid programs serve to promote the provision of high quality patient care for transplant recipients. In order for a transplant program to participate with Medicare, the program is required to meet certain conditions of participation pertaining to data submission, clinical experience, and outcome requirements.[24] The outcomes evaluated are a transplant center's observed number of patient deaths and graft failures 1-year post transplant, as compared to the transplant center's expected number of patient deaths

[21] American Kidney Fund. "Kidney failure/ESRD." http://www.kidneyfund.org/kidney-disease/kidney-failure/#What_causes_kidney_failure? Accessed May 4, 2016.; Mayo Clinic. "Diseases and Conditions: Acute liver failure." http://www.mayoclinic.org/diseases-conditions/liver-failure/basics/prevention/con-20030966. Accessed May 4, 2016.; Mayo Clinic. "Diseases and Conditions: Heart failure." http://www.mayoclinic.org/diseases-conditions/heart-failure/basics/prevention/con-20029801. Accessed May 4, 2016.

[22] National Kidney Foundation. "Diabetes- A Major Risk Factor for Kidney Disease." https://www.kidney.org/atoz/content/diabetes. Accessed May 4, 2016.; Mayo Clinic. "Diseases and Conditions: Acute liver failure." http://www.mayoclinic.org/diseases-conditions/liver-failure/basics/prevention/con-20030966. Accessed May 4, 2016.; Mayo Clinic. "Diseases and Conditions: Heart failure." http://www.mayoclinic.org/diseases-conditions/heart-failure/basics/prevention/con-20029801. Accessed May 4, 2016.

[23] Nemati, E., Einollah, B., Pezeshki, L., Porfazian, V. and Fettahi (2014). Does Kidney Transplantation with Deceased or Living Donor Affect Graft Survial? *Nephro-Urology Monthly*. July 6(4):e12182; Orandi, B.J, Luo, X. Massie, A.B., Garonzik-Wang, J.M., Lonze, B.E., Ahmed, R. VanArendonk, K.J., Stegall, M.D., Jordan, S.C., Oberholzer, J., Dunn, T.B., Ratner, L.E., Kapur, S., Pelletier, R.P., Roberts, J.P., Melcher, M.L., Singh, P., Sudan, D.L., Posner, M.P., El-Amm, J.M., Shapiro, R., Cooper, M., Lipkowitz, G.S., Rees, M.A., Marsh, C.L., Sankari, B.R., Gerber, D.A., Nelson, P.W., Wellen, J., Bozorgzadeh, A., Gaber, A.O., Montgomery, R.A., and Segev, D.L. (2016). Survival Benefit with Kidney Transplants from HLA-Incompatible Live Donors. *The New England Journal of Medicine*. 374: 940-50.

[24] 42 CFR §482.80

and graft failures after risk adjustment.[25] Only a few types of organ transplant centers are exempt from the performance outcome requirements in 42 CFR §482.80 (c)(2). Requiring all organ transplant programs in Maryland to participate with Medicare and Medicaid assures that the quality of programs will be closely tracked. In addition, the requirements that Maryland's organ transplant programs maintain certification from UNOS and that Maryland's stem cell transplant programs meet Foundation for the Accreditation of Cellular Therapy (FACT) requirements promote the provision of high quality patient care.

The literature on the relationship between volume and outcomes for transplant programs is mixed and varies among organ types. For example, two studies found that one-year graft and patient survival outcomes for kidney transplant programs are associated with higher volume programs, but neither of these studies identified a clear minimum volume threshold.[26] Another 2009 study concluded that center volume is not a significant factor affecting patient survival.[27] The authors of this study noted that its contrary findings may be attributed to the study design, which incorporated an analysis period from the time of listing for a transplant rather than only post-transplant events.[28] For lung transplants, one study concluded that high volume lung transplant centers did not have lower rates of postoperative complications compared to low volume lung transplant centers, but that low case volume was a significant risk factor for higher mortality rates at 90 days, one year, and five years post-transplant.[29] Another study also concluded that high lung transplant center volume is associated with long-term survival, but other unidentified characteristics of centers also significantly affect outcomes.[30]

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[25] 42 CFR §482.80(c)(1)

[26] Schold J.D., Buccini, L.D., Srinivas, T.R., Srinivas, R.T., Poggio, E.D., Flechner, S.M., Soria, C., Segev, D.L., Fung, J., and Goldfarb, D.A. (2013). The Association of Center Performance Evaluations and Kidney Transplant Volume in the United States. *American Journal of Transplantation*. 13:67-75; Axelrod, D.A., Gidinger, M.K., McCullough, K.P., Lechtman, A.B., Punch, J.D., and Merion, R.M. (2004). Association of Center Volume with Outcome After Liver and Kidney Transplantation. *American Journal of Transplantation*. 4:920-927;

[27] Schold, J.D., Harman, J.S., Chumbler, N.R., & Meier-Kriesche, H.U. (2009). The pivotal impact of center characteristics on survival of candidates listed for deceased donor kidney transplantation. *Medical Care.* Feb; 47(2): 146-153.

[28] Ibid.

[29] Kilic, A., George, T.J., Beaty, C.A., Merlo, C.A., Conte, J.V., Shah, A.S. (2012). The effect of center volume on the incidence of postoperative complications and their impact on survival after lung transplantation. *Journal of Thoracic Cardiovascular Surgery*. Dec;144(6):1502-8.

[30] Thabut, G., Christie, J.D, Kremers, W.K., Fournier, M., and Halpern, S.D. (2010). Survival Differences Following Lung Transplantation Among US Transplant Centers. *Journal of the American Medical Association*. July 7; 304 (1): 53-60.

Studies of heart transplant programs have consistently concluded that transplant centers with higher volumes have lower mortality rates and fewer post-operative complications. A systematic review of studies examining the relationship between heart transplant center volume and patient mortality concluded that risk adjusted mortality was lower at high-volume centers compared to intermediate and low-volume centers.[31] Another study that examined both post-transplant graft survival at one year, primary graft failure within 30 days, and morbidity during transplant hospitalization concluded that both post-transplant graft failure within one year and primary graft failure are associated with low annual transplant center volume.[32] This study also concluded that the relationship between volume and outcomes is stronger for patients at higher risk for adverse outcomes; high risk patients had superior outcomes at high and intermediate volume centers compared to low-volume centers.[33] Another study that examined one-year mortality for orthotopic[34] heart transplant patients reached similar conclusions; high volume centers minimize the effects of risk for transplant recipients, and low volume centers amplify the odds of one-year mortality associated with higher risk recipients.[35] This study also noted that as transplant volume increases from zero to ten orthotopic heart transplants, there is a steep decline in one-year mortality across all four tiers of recipient risk.[36] Despite reaching this conclusion, the authors of this study cautioned that certain low volume centers achieve excellent outcomes across the spectrum of recipient risk and directing more high risk patients to high volume centers could have negative consequences as a result of patient travel that affects post-operative compliance.[37] Another study investigated the relationship between heart transplant center volume and complication-driven mortality.[38] This study concluded that low-volume transplant centers had a

[31] Pettit, S.J., Jhund, P.S., Hawkins, N.M., Gardner, R.S., Haj-Yahia, S., McMurray, J.J., and Petrie. (2012). How small is too small? A systematic review of center volume and outcome after cardiac transplantation. *Circulation. Cardiovascular Quality and Outcomes.* Nov; 5(6):783-90.

[32] Russo, M.J., Iribarne, A., Easterwood, R., Ibrahimiye, A.N., Davide, R., Hong, K.N., Asccheim, D.D., Gelijns, A.C., and Naka, Y. (2010) Post-Heart Transplant Survival Is Inferior at Low-Volume Centers Across All Risk Strata. *Circulation*. 122:S85-S91.

[33] Ibid.

[34] An orthotopic heart transplant entails first removing the recipient's failing heart and then replacing it with a donor's heart.

[35] Arnaaoutakis, G.J., George, T.J., Allen, J.G., Russell, S.D., Shah, A.S., Conte, J.V., and Weiss, E.S. (2012). Institutional volume and the effect of recipient risk on short-term mortality after orthotopic heart transplant. *Journal of Thoracic Cardiovascular Surgery.* Jan; 143 (1):157-67.

[36] Ibid.

[37] Ibid.

[38] Grimm, J.C., Kilic, A., Shah, A.S., Trent Magruder, J., Valero, V. 3rd, Dungan, S.P., Russell, S.D., Tedford, R.J., Whitman, G.J., and Sciortino, C.M. (2015). The influence of institutional volume on the incidence of complications and their effect on mortality after heart transplantation. *Journal of Heart Lung Transplant.* Nov; 34(11):1390-7.

greater incidence of complications resulting in significantly reduced 90-day, one-year, and five-year risk adjusted survival rates.[39] However, the authors also noted that the causal basis for the difference could not be identified without examining additional variables not available through the database used.[40]

For liver transplants, multiple studies have concluded that outcomes, such as mortality rates, are better for high volume liver transplant centers compared to low volume centers. One study concluded that one-year mortality rates, after risk adjustment were significantly higher at low volume liver transplant centers compared to high volume liver transplant centers.[41] Two studies concluded that for high and very high risk patients, mortality rates were lower at high volume transplant programs compared to low volume programs.[42] Another study examined the impact of liver transplant center volume on graft failure and concluded that graft loss was not associated with transplant center volume.[43] However, this study concluded that other center characteristics have a significant effect, but only some of the sources of this effect could be identified.[44]

Although studies of the relationship between organ transplant center volume and patient outcomes fail to conclusively demonstrate that concentrating volume at as few transplant centers as possible would likely lead to optimal patient outcomes, there may be other reasons to favor higher volume centers. One benefit of maintaining fewer, higher volume, transplant centers may be more efficient use of hospital resources.[45] Minimum volume requirements for organ transplantation programs are necessary to maintain the skills of the entire transplant team and to

[39] Ibid.
[40] Ibid.
[41] Axelrod, D.A, Guidinger, M.K., McCullough, K.P., Leichtman, A.B., Punch, J.D., and Merion, R.M. (2004). Association of Center Volume with Outcome After Liver and Kidney Transplantation. *American Journal of Transplantation.* 4:920-927.
[42] Ozhathil, D.K., Li, Y., Smith, J.K., Tseng, J.F., Saidi, R.F., Bozorgzadeh, A. and Shah, S.A. (2011). Effect of centre volume and high donor risk index on liver allograft survival. *HPB (Oxford*) Jul;13(7):447-53;Macomber, C.W., Shaw, JJ, Santry, H. Saidi, R.F., Jabbour, N., Tseng, J.F., Bozorgzadeh, A., and Shah, S.A. (2012) Center volume and resource consumption in liver transplantation. HPB (Oxford) Aug; 14(8): 554-559.
[43] Asrani, S.K., Kim, W.R., Edwards, E.B, Larson, J. BS, Thabut, G., Kremers, W.K., Therneau, T.M., and Heimbach, J. (2013). Impact of Center on Graft Failure after Liver Transplantation. *Liver Transplant*. September; 19(9):957-964.
44 Ibid.
[45] Macomber, C.W., Shaw, J.J., Santry, H., Saidi, R.F., Jabbour, N., Tseng, J.F., Bozorgzadeh, A., and Shah, S.A. (2012). HPB (Oxford) Aug; 14(8): 554-559.

assure the provision of high quality patient care, as indicated by the conditions of participation in Medicare and Medicaid for clinical experience.[46]

In addition to transplant center volume affecting patient outcomes, race, socioeconomic status, and other factors have been linked to patient outcomes following organ transplants.[47] One recent national study of outcomes for kidney transplant recipients concluded that difference in outcomes for Caucasian and African American adults who received a living donor kidney (LDK) or deceased donor kidney (DDK) have improved over the period 1990 to 2012, but differences still persist.[48] Over this period, five-year graft loss for DDK transplant improved from 51.4% to 30.6% for African American patients and from 37.3% to 25.0% for Caucasian patients.[49] In addition, African American patients in the first cohort were 39% more likely than Caucasian patients to experience a five-year graft loss compared to 10% more likely for the most recent cohort.[50] For the one-year and three-year graft outcomes of both LDK and DDK transplants, in the most recent cohort there was not a statistically significant difference between African American and Caucasian patients.[51] An earlier national study, for the period 1999-2008, that evaluated outcomes for kidney transplant patients had concluded that long term outcomes for both DDK and LDK were worse for African Americans compared to other racial or ethnic groups.[52] This study also concluded that DDK transplants for Asian and Hispanic individuals have the best outcomes with respect to

[46] 42 CFR §482.80(b)

[47] Fan, P.Y., Ashby, V.G., Fuller, D.S., Boulware, L.E., Kao, A., Norman, S.P., Randall, H.B., Young, C., Kalbfleisch, J.D., and Leichtman, A.B. Access and Outcomes Among Minority Transplant Patients, 1999-2008, with a Focus on Determinants of Kidney Graft Survival. *American Journal of Transplantation*. 10 (402): 1090-1107; Axelrod, D.A., Dzebisashvili, N., Schnitzler, M.A., Salvalaggio, P.R., Segev, D.L., Gentry, S.E., Tuttle-Newhall, J., and Lentine, K.L. (2010). The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Are Travel on Kidney Transplant Access and Outcomes. *Clinical Journal of the American Society of Nephrology*. 5(12): 2276-2288; Taber, D.J., Hamedi, M., Rodrigue, J.R., Gebregziabher, M.G., Srinivas, T.R., Baliga, P.K., Egede, and L.E. (2015). Quantifying the Race Stratified Impact of Socioeconomics on Graft Outcomes in Kidney Transplant Recipients. *Transplantation.* Goldfarb-Rumyantzev, A.S., Sandhu, G.S., Baird, B.C., Khattak, M., Barenbaum, A., and Hanto, D.W. (2011). Social Adaptability Index predicts access to kidney transplantation. *Clinical Transplantation*. Nov-Dec;25(6): 834-42.

[48] Purnell, T.S., Luo, X., Kucirka, L.M., Cooper, L.A., Crews, D.C., Massie, A.B., Boulware, L.E., and Segev, D.L. (2016). Reduced Racial Disparity in Kidney Transplant Outcomes in the United States from 1990 to 2012. *Journal of American Society of Nephrology.* doi: 10.1681/ASN.2015030293.

[49] Ibid.

[50] Ibid.

[51] Ibid.

[52] Fan, P.Y., Ashby, V.G., Fuller, D.S., Boulware, L.E., Kao, A., Norman, S.P., Randall, H.B., Young, C., Kalbfleisch, J.D., and Leichtman, A.B. (2010). Access and Outcomes Among Minority Transplant Patients, 1999-2008, with a Focus on Determinants of Kidney Graft Survival. *American Journal of Transplantation*. 10 (402): 1090-1107.

mortality and graft survival at one-year, five-years, and ten-years post-transplant.[53] A national study of kidney transplant candidates listed in the period 1999 to 2009 concluded that individuals in the highest socioeconomic quartile had increased access to transplants compared to those in the lowest socioeconomic status and lower mortality rates while on the waitlist.[54] The authors of this study noted that better access for high socioeconomic individuals was largely driven by a higher likelihood of a living donor transplant.[55]

Access to Care

Many factors affect an individual's access to organ transplant services. Barriers to access may be financial, social, biological, or geographic. With regard to geographic access, this Chapter maintains the long-standing three-hour, one-way drive time standard for reasonable geographic access. Currently, over 95% of Maryland's population has access to organ transplant services within a three-hour, one-way drive time. Geography also has historically played a key role in the UNOS allocation system for organs, by prioritizing access within OPOs and regions based on the source of the organ donor.[56] Biologically, certain individuals have more potential organ matches, and the extent to which a donor organ is compatible with a potential recipient historically has strongly influenced access to an organ transplant.[57] An individual's access to health insurance and the financial resources to cover the costs of health care preceding and following an organ transplant may also strongly determine access to an organ transplant. A person's financial resources may influence his or her access to an organ transplant because a person must be able to cover the cost, over their lifetime, of the immunosuppressive drugs required to minimize the chances of graft failure and to cover costs that may not be covered by insurance or other third-party payers.[58] Social factors may affect an individual's risk for diseases

[53] Ibid.
[54] Axelrod, D.A., Dzebisashvili, N., Schnitzler, M.A., Salvalaggio, P.R., Segev, D.L., Gentry, S.E., Tuttle-Newhall, J., and Lentine, K.L. (2010). The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Are Travel on Kidney Transplant Access and Outcomes. *Clinical Journal of the American Society of Nephrology*. 5(12): 2276-2288
[55] Ibid.
[56] Davis A.E., Mehrotra S, Kilambi V., Kang J., McElroy L., Lapin B., Holl J, Abecassis M, Friedewald J.J., and Ladner D.P. (2014). The effect of the Statewide Sharing variance on geographic disparity in kidney transplantation in the United States. *Clinical Journal of the American Society of Nephrology*. 9(8):1449-60.
[57] Malek, S.K., Keys, B.J., Kumer, S., Milford, E., and Tullius (2010) Racial and ethnic disparities in kidney transplantation. *Transplant International*. http://onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.2010.01205.x/pdf
[58] United Network for Organ Sharing. "What Every Patient Needs to Know." https://www.unos.org/wp-

that lead to the need for an organ transplant, access to a living donor for a kidney transplant, and the pursuit of a deceased donor kidney.[59]

For over a decade, there has been an ongoing effort to reform the UNOS allocation system for various types of organs in order to provide more equitable access to organs, such as kidneys.[60] For the UNOS kidney allocation system, up until December 4, 2014, the highest priority candidates for a transplant were those with perfect matches in human leukocyte antigen genes because better matching of these genes reduces the probability of graft failure due to the transplant recipient's immune system attacking cells recognized as foreign.[61] In addition, a transplant candidate in the same OPO as the organ donor was also given higher priority, followed by those in the same UNOS region.[62] Under the new kidney allocation system, candidates with high calculated panel-reactive antibody scores at or near 100%, a candidate group with low rates of transplantation due to incompatibility with most donors, have higher priority.[63] The new kidney allocation system also increases access for historically disadvantaged candidates, including African Americans, who may be on dialysis for long periods prior to getting on the waiting list for kidneys, by using time on dialysis to determine priority for a kidney rather than time on the waiting list.[64]

Similar to the update in UNOS allocation policies for kidney transplants, the UNOS allocation policies for liver transplantation changed in June 2013 in order to provide a more

content/uploads/unos/WEPNTK.pdf. Accessed April 18, 2016.

[59] Purnell, T.S., Hall, Y.N., and Boulwar, L.E. (2012). Understanding and Overcoming Barriers to Living Kidney Donation among United States Racial and Ethnic Minorities. Advances in Chronic Kidney Disease. July; 19(4):244-251; Patzer R.E., Perryman J.P., Schrager J.D., Pastan S., Amaral S., Gazmararian J.A., Klein M., Kutner N., and McClellan W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation*. February; 12(2):358-368.

[60] Stewart, D.E., Kucheryavaya, A.Y., Klassen, D.K., Turgeon, N.A., Formica, R.N., and Aeder, M.I. (2016) Changes in Deceased Donor Kidney Transplantation One Year After KAS Implementation. *American Journal of Transplantation*. March 2: 1-14.

[61] Daw, J. (2015). Explaining the Persistence of Health Disparities: Social Stratification and the Efficiency-Equity Trade-off in the Kidney Transplantation System. *American Journal of Sociology*. 120(6): 1595-1640.

[62] Ibid.

[63] Stewart, D.E., Kucheryavaya, A.Y., Klassen, D.K., Turgeon, N.A., Formica, R.N., and Aeder, M.I. (2016) Changes in Deceased Donor Kidney Transplantation One Year After KAS Implementation. *American Journal of Transplantation*. March 2: 1-14; Massie, A.B., Luo, X., Lonze, B.E., Desai, N.M., Bingaman, A.W., Cooper, M., and Segev, D.L. (2015) Early Changes in Kidney Distribution under the New Allocation System. *Journal of the American Society of Nephrology*. December 17. doi: 10.1681/ASN.2015080934

[64] Ibid.

equitable system. Under the new allocation policies, referred to as "Share 35," patients with a Model for End-stage Liver Disease (MELD) score higher than 35 have priority. The goals of the policy change were to reduce the mortality of patients with higher MELD scores on the waiting list and to more equitably offer liver transplants to those who most need them. A study evaluating the mortality of patients on the liver transplant waitlist before and after the implementation of Share 35 found that, nationally, patient mortality rates on the waitlist decreased by 30% among patients with a MELD score over 30, while there was no change for patients with a MELD score of 30 or less.[65] A second study also concluded that, nationally, mortality rates were not worse following implementation of Share 35; however, this study identified regional variation, with mortality rates worsening in some regions following the policy changes.[66]

The demand for organs has grown rapidly over time and far exceeds the supply of organs available from deceased individuals. In 1991, there were 6,953 organ donors, 15,756 transplants, and 23,198 people on waiting lists for organs.[67] In 2014, although the number of donors approximately doubled to 14,412, and the number of transplants similarly increased to 29,532, the number of people on the waitlist increased to 123,851.[68] Per capita, for African Americans and other minorities, the need for organ transplants is higher than for Caucasians.[69] In addition, organ donor consent rates are lower for minorities; one study found that the consent rate among Caucasians was 77.0 percent compared to 67.5 percent for Hispanic Americans, 54.9 percent for African Americans, and 48.1 percent for Asian Americans.[70] The lower consent rates were attributed to personal, cultural, and religious beliefs.[71] The rates of donation for some organs, such as kidneys, have increased over time for African Americans, and the rates for kidney

[65] Massie, A.B., Chow, E.K.H., Wickliffe, C.E., Luo, X., Gentry, S.E., Mulligan, D.C., and Segev, D.L. (2015). Early Changes in Liver Distribution Following Implementation of Share 35. *American Journal of Transplantation*. 15: 659-667.
[66] Halazun, K.J., Mathur, A.K., Rana, A.A., Massie, A.B., Mohan, S., Patzer, R.E., Wedd, J.P., Samstein, B., Subramanian, R.M., Campos, B.D., Knechtle, S.J. (2016). One Size Does not Fit All- Regional Variation in the Impact of the Share 35 Liver Allocation Policy. *American Journal of Transplantation*; 16: 137-142.
[67] U.S. Department of Health and Human Services. "The Gap Continues to Widen." http://www.organdonor.gov/about/graphdescription.html. Accessed April 13, 2016.
[68] Ibid.
[69] U.S. Department of Health and Human Services. "African Americans and Organ Donation." http://www.organdonor.gov/minortyaa/ Accessed April 29, 2016.
[70] Goldberg D.S., Halpern S.D., and Reese P.P. (2013). Deceased Organ Donation Consent Rates among Racial and Ethnic Minorities and Older Potential Donors. *Critical Care Medicine*. 41(2): 496-505.
[71] Ibid.

donation by African Americans exceeded those of Caucasians beginning around 2009.[72] In 2013, donation rates for African Americans was very similar to the rates for Asian Americans, the group with the highest rate.[73] However, the need for organ transplants is greater among minorities,[74] and the increased supply over time does not appear to have resulted in significantly shorter waiting times for these populations, given rapidly expanding organ transplant waitlists.

For individuals who require a kidney or liver, living donation is an option. Living donations promise better outcomes for patients[75] and reduced waiting times for an organ transplant. However, multiple studies have identified racial disparities with regard to access to living donors.[76] Socioeconomic status has also been identified as a barrier for some potential living donors.[77] A study that evaluated access to and utilization of living donors for liver transplants found that African American, Hispanic American, and Asian American patients with liver disease were much less likely than Caucasian patients to receive a living donor liver transplant.[78] This study attributed

[72] United States Renal Data System (USRDS). "Chapter 7: Transplantation." http://www.usrds.org/2015/view/v2_07.aspx. Accessed April 15, 2016.
[73] Ibid.
[74] U.S. Department of Health and Human Services. "African Americans and Organ Donation." http://www.organdonor.gov/minortyaa/. Accessed April 29, 2016.
[75] Orandi, B.J, Luo, X. Massie, A.B., Garonzik-Wang, J.M., Lonze, B.E., Ahmed, R. VanArendonk, K.J., Stegall, M.D., Jordan, S.C., Oberholzer, J., Dunn, T.B., Ratner, L.E., Kapur, S., Pelletier, R.P., Roberts, J.P., Melcher, M.L., Singh, P., Sudan, D.L., Posner, M.P., El-Amm, J.M., Shapiro, R., Cooper, M., Lipkowitz, G.S., Rees, M.A., Marsh, C.L., Sankari, B.R., Gerber, D.A., Nelson, P.W., Wellen, J., Bozorgzadeh, A., Gaber, A.O., Montgomery, R.A., and Segev, D.L. (2016). Survival Benefit with Kidney Transplants from HLA-Incompatible Live Donors. *The New England Journal of Medicine*. 374: 940-50.
[76] Hall, E.C., James, N.T., Garonzik Wang J.M., Berger, J.C., Montgomery, R.A., Dagher, N.N., Desai, N.M., and Segev, D.L. (2012) Center-level factors and racial disparities in living donor kidney transplantation. *American Journal of Kidney Disease*. 59(6):849-57; Purnell TS[1], Hall YN, Boulware LE. (2012). Understanding and Overcoming Barriers to Living Kidney Donation among United States Racial and Ethnic Minorities. *Advances in Chronic Kidney Disease*. 19(4):244-251; Nobel, Y.R., Forde, K.A., Wood, L., Cartiera K., Munoz-Abraham, A.S., Yoo, P.S., Abt, P.L., and Goldberg, D.S. (2015). Racial and ethnic disparities in access to and utilization of living donor liver transplants. *Liver Transplantation*. 21(7): 904-13; Weng, F.L., Reese, P.P., Mulgaonkar, S., and Patel, A.M. (2010). Barriers to Living Donor Kidney Transplantation among Black or Older Transplant Candidates. *Clinical Journal of the American Society of Nephrology*. 5(12): 2338-2347; Gore, J.L., Danovitch, G.M., Litwin, M.S., Pham, P.T.T., and Singer, J.S. (2009). Disparities in the Utilization of Live Donor Renal Transplantation. *American Journal of Transplantation*. 9: 1124-1133.
[77] Axelrod, D.A., Dzebisashvili, N., Schnitzler, M.A., Salvalaggio, P.R., Segev, D.L., Gentry, S.E., Tuttle-Newhall, J., Lentine, K.L. (2010). The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Are Travel on Kidney Transplant Access and Outcomes. *Clinical Journal of the American Society of Nephrology*. 5(12): 2276-2288; Gore, J.L., Danovitch, G.M., Litwin, M.S., Pham, P.T.T., and Singer, J.S. (2009). Disparities in the Utilization of Live Donor Renal Transplantation. *American Journal of Transplantation*. 9: 1124-1133.
[78] Nobel, Y.R., Forde, K.A., Wood, L., Cartiera K., Munoz-Abraham, A.S., Yoo, P.S., Abt, P.L., and Goldberg, D.S. (2015). Racial and ethnic disparities in access to and utilization of living donor liver transplants. *Liver Transplantation*. 21(7): 904-13.

the difference to fewer inquiries by potential donors for minorities compared to Whites.[79] A study evaluating access to living kidney donors also concluded that African Americans, certain other minorities (Asian, Pacific Islander, Native American), and patients of low socioeconomic status has lower odds of a transplant from a living kidney donor.[80] A national study that examined factors affecting racial disparities in living donor kidney transplants for the period 1995-2007 concluded that racial parity was not seen at any transplant center; the odds of African Americans receiving a living donor kidney transplant ranged from 35% to 76% lower odds compared to non-African Americans.[81] The trend in the number of living donors by race over the period 1996-2013 indicates that the number of kidney transplants from living donors to recipients who are African American, Asian American, Native American, or other races has increased only slightly, suggesting that disparities continue to persist.[82]

Unlike many other types of health care services regulated through the CON process, access to an organ transplant is largely based on a separate federal regulatory system. The Commission primarily has the ability to affect access to organ transplants through regulating the number of organ transplant programs, which in turn affects the competitiveness of the market for organ transplant services. A few studies have examined the relationship between competition among organ transplant centers and patient outcomes. One study found that greater market competition is associated with increased patient mortality and graft failure due to the more aggressive use of riskier kidneys, but also concluded that these outcomes are still an improvement over outcomes for patients on chronic dialysis.[83] Another similar study that incorporated distance to the other transplant centers in the same DSA in addition to measures of market competition, concluded that both greater density of transplant centers and greater competition were associated with worse graft outcomes, and both randomly distributed centers within a DSA and dispersed centers within a DSA were associated with better patient survival; DSAs with a single transplant

[79] Ibid.
[80] Gore, J.L., Danovitch, G.M., Litwin, M.S., Pham, P.T.T., and Singer, J.S. (2009). Disparities in the Utilization of Live Donor Renal Transplantation. *American Journal of Transplantation*. 9: 1124-1133.
[81] Hall, E.C., James, N.T., Garonzik Wang J.M., Berger, J.C., Montgomery, R.A., Dagher, N.N., Desai, N.M., Segev, D.L. (2012) Center-level factors and racial disparities in living donor kidney transplantation. *American Journal of Kidney Disease*. 59(6):849-57
[82] United States Renal Data System (USRDS). "Chapter 7: Transplantation." http://www.usrds.org/2015/view/v2_07.aspx. Accessed April 15, 2016.
[83] Adler, J.T., Sethi, R.K.V., Yeh, H., Markmann, J.F., Nguyen, L.L. (2014). Market competition influences renal transplantation risk and outcomes. *Annals of Surgery*. 260: 550-557.

center or a clustered arrangement of centers was not associated with patient survival.[84] Market competition was not associated with a higher number of transplants.[85] Another study evaluated the impact of market competition among kidney transplant centers on waitlisting of patients for a kidney transplant. This study concluded that when there is strong competition, all of the transplant centers in a state tend to waitlist more patients for kidney transplants.[86] A study of the impact of market competition among liver transplant centers concluded that greater competition is associated with the inclusion of higher risk patients on waiting lists and more transplants for higher risk patients, with resulting higher costs and worse patient outcomes, including both worse graft survival and higher mortality.[87] Overall, these studies indicate that increasing competition may have both positive and negative consequences for patients.

Policies

The broad policy objectives shown below guide the Commission's regulation of the supply and distribution of organ transplantation services in Maryland and serve as a foundation for the standards in this State Health Plan chapter.

Policy 1: **Organ transplantation services will be provided in the most cost effective manner possible consistent with safely and effectively meeting the health care needs of appropriate patients.**

Policy 2: **Quality will be promoted and evaluated based on the performance measures and standards adopted by CMS for organ transplantation centers.**

Policy 3: **Community education and outreach will be actively promoted and facilitated by all hospitals providing organ transplantation to reduce the prevalence of end stage organ disease, and demand for organ transplantation. Likewise, all hospitals providing organ**

[84] Adler, J.T., Yeh, H., Markmann, J.F., and Nguyen, L. (2015). Temporal Analysis of Market Competition and Density in Renal Transplantation Volume and Outcome. *Transplantation.* 100(3): 670-7.
[85] Ibid.
[86] Cho, P.S., Saidi, R.F., Cutie, C.J., and Ko, D.S.C. (2015). Competitive Market Analysis of Transplant Centers and Discrepancy of Wait-Listing of Recipients for Kidney Transplantation. *International Journal of Organ Transplantation Medicine.* 6(4): 141-149.
[87] Halldorson, J.B., Paarsch, H.J., Dodge, J.L., Segre, A.M., Lai, J., and Roberts, J.P. (2013). Center Competition and Outcomes Following Liver Transplantation. *Liver Transplantation*. 19:96-104.

transplantations will also actively promote and facilitate programs to increase the availability of donor organs. The Commission supports the use of Maryland's Organ and Tissue Donation Awareness Fund for education and outreach and the development of other regional or statewide initiatives to promote organ donation.

Policy 4: All hospitals providing organ transplantation will actively educate patients about how to get on the organ wait list and how to pay for organ transplantation and important follow-up services.

Policy 5: Organ transplantation services will be accessible consistent with efficiently meeting the health care needs of patients.

Policy 6: A hospital providing organ transplantation will continuously and systematically work to improve the quality and safety of patient care. This includes planning, implementing, and optimizing the use of electronic health record systems and electronic health information exchange that contributes to infection control, care coordination, patient safety, and quality improvement.

.04 Certificate of Need Docketing Rules

The Commission will only docket an application for a new organ transplant program if:

A. All existing non-federal organ transplant programs in the health planning region have been operating at or above the applicable annual threshold case volume for at least three years prior to the filing of the application unless an organ transplant program in the health planning region has been designated as a member not in good standing by the Organ Transplant and Procurement Network. The volume of an organ transplant program designated as a member not in good standing will be disregarded when determining if all organ transplant programs have met the annual threshold volume requirements for the prior three years; and

B. All of the existing non-federal organ transplant programs in the health planning region engaged in transplantation of the same organ type as the proposed new program have been in operation for at least three years.

Table 2: Annual Threshold Case Volume Requirements by Type of Organ

Type of Organ	Annual Threshold 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, and Others, to be determined by the Commission as needed.	No requirement
Vascular Composite Allograft	No requirement

.05 Standards

A. General Standards

(1) An applicant seeking a Certificate of Need for an organ transplantation service shall address and meet the general standards in COMAR 10.24.10.04A in its application.

(2) Each Maryland transplant program shall agree to comply with all requirements of CMS and UNOS certification and, if applicable, accreditation by the Foundation for the Accreditation of Cellular Therapy.

(a) Each organ transplant program shall be certified by UNOS within the first year of operation.

(b) Each hematopoietic stem cell bone marrow transplant program shall be accredited by the Foundation for the Accreditation of Cellular Therapy within the first two years of operation.

B. Project Review Standards

(1) Need

An applicant shall demonstrate that a new or relocated organ transplant center is needed. Closure of an existing service, in and of itself, is not sufficient to demonstrate the need to establish a new organ transplant center.

An applicant shall address:

(a) The ability of the hospital to increase the supply or use of donor organs for patients served in Maryland. This may include, but is not limited to, technology innovations and living donation initiatives.

(b) Projected volume shifts from programs in the two OPOs that serve Maryland residents.

(c) The utilization trends for the health planning region in which the proposed program will be located and the jurisdictions in which the population to be served reside. If the proposed program will be located in a jurisdiction that shares a border with another health planning region, then the utilization trends in each health planning region shall be addressed.

(2) Minimum Volume Requirements

(a) An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum annual case volume as defined by this Plan within the first three years of operation and will likely continue to sustain at least the minimum annual case volume in subsequent years.

(b) As a condition of approval, an applicant shall agree that it will close its organ transplant program under the following circumstances:

(i) After meeting the minimal annual case volume required for a new program, the program is unable to sustain the minimum annual case volume for any two consecutive years, and it is unable:

1. To provide an explanation acceptable to the Commission as to why it failed to maintain the minimum annual case volume; and

2. To develop a credible plan for achieving the minimum annual threshold case volume that is approved by the Commission; or

(ii) The program fails to achieve the minimum annual case volume by a deadline established by the Commission as a result of the program's failure to achieve the minimum annual case volume requirements.

Table 3: Minimum and Threshold

Case Volume Requirements by Organ Type **Organ Type**	**Minimum Annual Case Volume**
Kidney Adult Pediatric	 30 10
Liver	12
Pancreas /Heart Lung	No Volume Requirement
Heart	12
Lung	12
Hematopoietic Stem Cell: Autologous Allogeneic	 10 10
Intestine/Small Bowel, Islet Cells, Hepatocytes, and Others	No Volume Requirement

(3) Access

(a) Each type of organ transplant service should be accessible within a three-hour one-way drive time for at least 95 percent of Maryland residents.

(b) An applicant that seeks to justify the need for additional organ transplantation services on the basis of barriers to access shall:

(i) Present evidence to demonstrate that barriers to access exist, based on studies or validated sources of information

(ii) Present a credible plan to address those barriers. The credibility of the applicant's plan will be evaluated on whether research studies or empirical evidence from comparable projects support the proposed plan as a mechanism for addressing each barrier identified, whether the plan is feasible, and whether members of the communities affected by the project support the plan.

(c) Closure of an existing service, in and of itself, is not sufficient to demonstrate an access issue or the need to establish a new or replacement organ transplantation service.

(d) Travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way.

(4) Cost Effectiveness

An applicant shall demonstrate that the proposed establishment or relocation of an organ transplant program is cost-effective by providing:

(a) A demonstration that analyzes why existing programs cannot meet the need for organ transplants for the proposed population to be served.

(b) An analysis of how the establishment or relocation of the proposed organ transplant program will benefit the population to be served, quantifying these benefits to the extent feasible and documenting the projected annual costs of the proposed program over a period of at least five years.

(c) Estimates of the costs to the health care system as a whole and the benefits of the proposed program, quantifying the benefits to the extent feasible over a period of five years.

(5) Impact

(a) A new organ transplant program or relocation of an organ transplant program shall not interfere with the ability of existing programs to maintain at least the annual threshold case volumes defined in this Chapter; and

(b) A new organ transplant program shall not have an unwarranted adverse impact on the financial viability of another hospital's organ transplant program; and

(c) A new organ transplant program shall not have an unwarranted adverse impact on patient access to organ transplant services at another hospital, the quality of services provided, or patient outcomes following organ transplantation.

(d) An applicant shall provide documentation and analysis that supports:

(i) Its estimate of the impact of the proposed organ transplant program on patient volume at other organ transplant programs in the same health planning region and in other health planning regions that may be

impacted. The applicant shall quantify the shifts in case volume for each location; and

(ii) Describe the anticipated impact on access to transplant services for the population residing within a three-hour drive time of the proposed location, including financial and geographic access; and

(iii) Describe the anticipated impact on the quality of care for the population residing within a three-hour drive time of the proposed location.

(6) Certification and Accreditation

(a) An applicant for an organ transplant program shall be certified within the first year of operation by United Network for Organ Sharing.

(b) An applicant for a hematopoietic stem cell transplant program shall meet accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT) within the first three years of operation. An applicant shall apply and be FACT-accredited within 12 months of becoming eligible to apply for accreditation and shall maintain its accreditation thereafter.

(c) The hospital sponsoring an organ transplant program must be accredited by the Joint Commission.

(7) Health Promotion and Disease Prevention

An organ transplant program shall actively and continuously engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease and increasing the availability of donor organs. An applicant must describe the relevant preventive services designed to address those at greatest risk for end stage organ failure.

(8) Comparative Reviews

(a) In the case of a comparative review of applications in which all applicants have met all policies and standards, the Commission will give preference to the applicant with an established prevention or early intervention program addressing the specific medical conditions leading ultimately to transplantation.

(b) In evaluating the effectiveness of the program, the Commission will take into consideration:

(i) The applicant's demonstrated record of serving minority and indigent patients;

(ii) The applicant's demonstrated record of establishing programs for outreach to the minority and indigent populations; and

(iii) An evaluation of the effectiveness and efficiency of the intervention programs with respect to improved outcomes or improved health status of the populations served.

.06 Definitions.

(1) Health planning region means the geographic area designated by the United Network for Organ Sharing for each of the two Organ Procurement Organization serving Maryland residents.

(2) *Hematopoietic stem cell transplant* means a stem cell or bone marrow transplant procedure identified by the following International Classification of Diseases (9^{th} Revision, Clinical Modification) procedure codes: 41.00 through 41.09 or the 10^{th} edition procedure codes: 30230G0 through 30263G1.

(3) *Member Not in Good Standing* is a public designation of an OPTN member institution that has failed to meet key expectations for compliance with OPTN requirements. It could also apply to a member with a current situation that could pose a risk to the health and safety of transplant patients, living donors or other members of the public. This could involve a single adverse event or a pattern of unresolved behavior.

(4) *Organ* means a human kidney, liver, heart, lung, pancreas, bone marrow, and intestine, including esophagus, stomach, small intestine, and large intestine. It also includes vascular composite allografts.

(5) *Organ Procurement Organization (OPO)* means a federally designated organ procurement agency.

(6) *Organ Procurement and Transplantation Network* (OPTN) refers to the Organ Procurement and Transplantation Network, a national transplant network established by federal law (the National Organ Transplant Act of 1984) and federal regulations (the OPTN Final Rule).

(7) *Organ transplant services* means inpatient or outpatient services for patients preparing for and receiving an organ transplant, and the follow-up services directly related to the organ transplant.

(8) *Organ transplant* means surgical procedures involving the transplantation of organs, including hematopoietic stem cell transplant procedures.

(9) *Pediatric* refers to patients under age 18. A pediatric program is one that serves a majority of patients under age 18.

(10) A "*teaching hospital*" refers to a hospital that delivers medical care to patients, is committed to educational activities in the health professions, and provides clinical education and training to medical students, residents, and postgraduate fellows. A teaching hospital is distinguished, in large part, by its clinical research programs, where drugs, medical devices and treatment methods are developed and tested.

(11) *Transplant* means to graft or transfer an organ from one human body to another human body.

(12) *Transplantation* means the grafting of organs.