

TRANSPLANTATION SERVICES

I. INTRODUCTION

In 2017, a total of 34,770 organ transplants were performed in the United States using organs from both deceased and living donors.¹ This is a 3.4% increase over 2016 and marks the fifth consecutive record-setting year for transplants in the United States.² The four most common organs transplanted were kidney, liver, heart and lung with a record number of donor organs recovered and transplanted.³

With the increasing number of organ transplants occurring annually, the West Virginia Health Care Authority (Authority) recognizes that hospitals in the state may wish to pursue organ transplantation services.

The mission of the Authority is to ensure that West Virginians have appropriate access to quality, affordable health care services while protecting consumers from unnecessary duplication of services.

As a result, these standards address the necessary criteria which must be met to obtain a Certificate of Need (CON) to provide transplantation services in West Virginia. A separate CON must be obtained for the development of each new transplant service offered. A hospital that has obtained a CON to provide one type of transplantation service may not perform another type of transplantation service until a CON is obtained. Further, a hospital system must receive approval to provide a transplantation service at a specific hospital and the transplantation service may not be relocated to another hospital in the system without receiving a CON.

¹ <https://optn.transplant.hrsa.gov/news/deceased-organ-donors-in-us-exceeded-10-thousand-for-first-time-in-2017/>

² Ibid.

³ Ibid.

Covered Transplant Services:

Solid Organs:

Heart
Lungs
Liver
Pancreas
Kidney
Intestines

Bone Marrow

Solid organ transplantation is one of the most highly, federally regulated areas of medicine. Current standards require United Network of Organ Sharing (UNOS) certification via hospital membership in the Organ Procurement and Transplantation Network (OPTN) before any facility can initiate a transplant program. The OPTN membership application requires that all UNOS/OPTN required staff and resources be in place before approval or initiation of transplantation. Additionally, the Centers for Medicare and Medicaid Services (CMS) requires that a provider of solid organ transplant services be approved by UNOS/OPTN and perform an established minimum number of successful transplants. Once a transplant program is initiated, both UNOS and CMS mandate and monitor program quality through required patient and program outcome reporting and site visits.

CMS requires transplantation programs to meet the following conditions of participation:

Kidney:	3 procedures in year 1 and 10 for re-approval
Liver:	10 procedures
Heart:	10 procedures
Lung:	10 procedures
Pancreas:	no annual minimum
Intestines:	10 procedures
Heart/Lung:	no annual minimum

A bone marrow transplant, also called a stem cell transplant, may be autologous, allogeneic or syngeneic and may be used in the following situations:

- (1) To safely allow treatment of a condition with high doses of chemotherapy or radiation by replacing or rescuing bone marrow damaged by treatment;
- (2) To replace diseased or damaged marrow with new stem cells; and
- (3) To provide new stem cells, which can help directly kill cancer cells.⁴

Transplantation is a specialized health service that requires the most advanced levels of equipment and clinical expertise. As a result, transplantation services shall be limited to academic medical centers. The current volume of procedures performed in an approved transplant program will be considered in determining need for additional transplant programs in the state.

II. DEFINITIONS

Academic Medical Center means a facility that consists of a hospital and medical school. It combines clinical care with education and research to provide the best possible care using the most current technology and resources.

Allogeneic Bone Marrow Transplant means stems cells are removed from a person other than the patient (donor) and then placed in the patient's body to produce normal blood cells.

Autologous Bone Marrow Transplant means stem cells are removed from the patient's own body before treatment. The stem cells are stored in a freezer and then placed back in the patient's body to make normal blood cells.

Bone Marrow Transplant means a procedure to replace damaged or destroyed bone marrow by infusing healthy blood stem cells into the body.

⁴ <https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/about/pac-20384854>

Service Area means the county/counties which will be served by the proposed transplantation service.

Solid Organ Transplantation means the removal of an internal organ, which has a firm tissue consistency and is not hollow nor liquid, from the body and an organ from a donor is surgically implanted.

Syngeneic Bone Marrow Transplant means stem cells are removed from the patient's identical twin and then placed in the patient's body to produce normal blood cells.

Transplant Program means a component within a hospital that provides transplantation of a particular type of organ to include: heart, lung, liver, kidney, pancreas or intestine.⁵

III. NEED METHODOLOGY

An applicant proposing to provide solid organ transplantation services must demonstrate that:

- A. There is an unmet need for the proposed transplantation service, that the proposed service will not have a negative impact on current providers of the service, and that the proposed service is the most cost-effective alternative;
- B. It can delineate the service area by documenting the expected areas from which the facility is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services;
- C. It can document the expected number of procedures for the services to be provided by the facility for the population within the service area;

⁵ Centers for Medicare & Medicaid Services

- D. It can document or estimate the number of existing providers within the service area and the number of procedures performed by existing providers in the service area;
- E. There is an unmet need by demonstrating that the total expected number of procedures, less the number of procedures performed by existing providers in the service area, results in a difference that is equal to or greater than the following minimum thresholds:
- Kidney: 10 procedures in year 1 and 20 procedures thereafter
 - Liver: 10 procedures
 - Heart: 10 procedures
 - Lung: 10 procedures
 - Intestines: 2 procedures
 - Pancreas: 3 procedures
 - Heart/Lung: 2 procedures
- F. For heart transplant services only, the applicant must be an existing provider of cardiac catheterization diagnostic and therapeutic services and be an existing provider of cardiac surgery services.

An applicant proposing to provide bone marrow transplantation services must demonstrate that:

- A. There is an unmet need for the proposed transplantation service, that the proposed service will not have a negative impact on current providers of the service, and that the proposed service is the most cost-effective alternative;
- B. It can delineate the service area by documenting the expected areas from which the facility is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national

data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services;

- C. It can document the expected number of procedures for the services to be provided by the facility for the population within the service area;
- D. It can document or estimate the number of existing providers within the service area and the number of procedures performed by existing providers in the service area;
- E. There is an unmet need by demonstrating that the total expected number of procedures, less the number of procedures performed by existing providers in the service area, results in a difference that is equal to or greater than the following minimum thresholds:
 - Allogeneic: 10 procedures
 - Autologous: 5 procedures

IV. QUALITY

- A. The applicant must meet the quality requirements of UNOS/OPTN and CMS for solid tissue transplants.
- B. The applicant must meet the quality requirements of FACT (Foundation for the Accreditation of Cellular Therapy) for bone marrow transplants.
- C. The applicant shall provide documentation that the following solid organ transplant support will be in place prior to initiating services:
 - Director of solid organ transplant center;
 - Transplant surgeon and physician;
 - Clinical transplant coordinator;

- Independent living donor advocate if living donor transplants will be performed by the applicant;
 - Multidisciplinary transplant team – medicine, nursing, nutrition, social services, transplant coordination, and pharmacology; and,
 - Transplant center expertise – internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education regarding transplant services.
- D. The applicant must initiate communication to register with the federally designated organ procurement organization.
- E. Utilization review and quality assurance programs shall be maintained.
- F. The applicant must be accredited by The Joint Commission, Det Norske Veritas (DNV), or another accepted accreditation body.

V. CONTINUUM OF CARE

The applicant shall demonstrate that it has the ability to provide a full continuum of organ transplantation services for the patients and their families.

The applicant shall ensure that the following written policies and protocols for managing organ transplant patients are in place prior to initiating transplant services:

- A. Detailed plans for the management of each transplant patient by a multidisciplinary care team that includes the time waiting for an organ, the time as an inpatient, and the time after discharge;
- B. Coordination with the patient's primary care physician regarding follow-up care; and,

- C. If the hospital performs living donor transplants, detailed plans for the living donor that include the evaluation, donation and discharge phases.

VI. COST

Applicants shall demonstrate the financial feasibility of the proposal by providing an analysis of the cost-effectiveness of the proposed project to include:

- A. A three (3) year projection of revenues and expenses for the project;
- B. Evidence that sufficient capital is available to initiate and operate the proposed project;
- C. Evidence that financing arrangements are reasonable and secure;
- D. Documentation that all indigent persons needing the service can be served without jeopardizing the viability of the project; and,
- E. That the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals.

VII. ACCESSIBILITY

- A. Transplant services shall be provided based on patients' medical needs and appropriateness without regard to the source of referral or payment;
- B. The applicant shall provide written policies, which are non-discriminatory in terms of race, color, creed, age, ethnicity, sex, sexual preference, financial resources, or location of residence; and,

- C. The applicant must demonstrate that transplant services are accessible to the disabled in compliance with applicable state and federal laws.

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