SOLID ORGAN AND STEM CELL TRANSPLANTATION

1. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive:

a. Updates responsibilities for the Assistant Under Secretary for Health for Integrated Veteran Care regarding their role in transplant community care; Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer; National Director of Surgery (NDS); Chair, Transplant Surgical Advisory Board; Department of Veterans Affairs (VA) medical facility Chief of Staff; referring VA medical facility Director; and VA Transplant Center (VATC) medical facility Director regarding their participation in a kidney paired donation program (see paragraph 2).

b. Updates the policy paragraph to include use of community transplant centers and live donor care (see paragraph 1).

c. Updates the background paragraph to include information on the Transplant Referral and Cost Evaluation/Reimbursement (TRACER) application and live donor care (see paragraph 4).

d. Updates definitions for solid organ transplantation (see paragraph 5).

e. Updates terminology to identify bone marrow transplantation as stem cell transplantation and adds definition for stem cell transplant (see paragraph 5).

f. Adds definitions for dual listing to include dual listing options in VA and in the community, VA National Transplant Program, VATC, VA Transplant Program, live donor, live donor follow-up, kidney paired donation, support person, and transplant specific purpose funds (see paragraph 5).

2. RELATED ISSUES: VHA Directive 1042.01, Veteran Dialysis Care, dated December 28, 2023; VHA Directive 1101.03, Solid Organ, Tissue and Eye Donation, dated August 23, 2021; VHA Directive 1102.01(2), National Surgery Office; dated April 24, 2019; VHA Directive 1102.07, Organ Donation After Circulatory Death, dated January 28, 2021.

3. POLICY OWNER: The National Surgery Office (11SURG) is responsible for the contents of this directive. Questions may be addressed to the NDS at <u>vhaco.national.surgery.office@va.gov</u>.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document creation requirements in this directive.

5. RESCISSIONS: VHA Directive 2012-018(1), Solid Organ and Bone Marrow Transplantation, dated July 9, 2012, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of May 2030. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Thomas O'Toole, MD Acting Assistant Under Secretary for Health for Clinical Services and Chief Medical Officer

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution Lists on May 27, 2025.

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SOLID ORGAN AND STEM CELL TRANSPLANTATION

1. POLICY

It is Veterans Health Administration (VHA) policy that solid organ and stem cell transplantation care is provided to Veterans eligible for Department of Veterans Affairs (VA) care, at VHA-approved VA transplant centers (VATCs), at affiliate transplant centers, and at authorized community transplant centers participating in the Veterans Community Care Program (VCCP). This care includes pre- and post-transplantation health care for Veteran transplant recipients. It is also VHA policy that organ donation procedures and associated care and services are provided to live donors in connection with the transplant care of a Veteran. **AUTHORITY:** 38 U.S.C. §§ 1703(I), 1710, 1788, 7301(b), 8153; 38 C.F.R. §§ 17.38, 17.395, 17.4020(d).

2. RESPONSIBILITIES

a. Under Secretary for Health. The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Evaluating and approving, as appropriate, recommendations forwarded by the National Director of Surgery (NDS) for new transplant services at VA medical facilities. *NOTE:* For more information on clinical restructuring requests (CRR), see VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.

b. Chief Operating Officer. The Chief Operating Officer is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Overseeing VISNs to ensure the effectiveness of and compliance with this directive.

c. <u>Assistant Under Secretary for Health for Clinical Services/Chief Medical</u> <u>Officer.</u> The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for:

(1) Supporting National Surgery Office (NSO) with implementation and oversight of this directive.

(2) Supporting the development of mitigation or corrective actions to address noncompliance with this directive.

d. <u>Assistant Under Secretary for Health for Patient Care Services/Chief Nursing</u> <u>Officer.</u> The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for communicating the requirements of this directive to relevant Patient Care Services offices.

e. <u>Assistant Under Secretary for Health for Integrated Veteran Care.</u> The Assistant Under Secretary for Health for Integrated Veteran Care (IVC) is responsible for:

(1) Providing clinical support, education, and guidance to VISNs and VA medical facilities regarding standardized processes for authorization of transplant care provided outside of VA at a community transplant center under VCCP.

(2) Ensuring key quality indicators for transplantation care as defined by NSO are met for services authorized under VCCP and provided by the community transplant centers.

f. <u>Director, Medical Sharing Office.</u> The Director, Medical Sharing Office is responsible for:

(1) Providing oversight, education, support, and guidance to VISNs and integrated affiliate VA transplant centers regarding standardized processes for establishing regional sharing agreements with affiliated transplant centers to facilitate transplantation care for Veterans under the authority of 38 U.S.C. § 8153. **NOTE:** See VA Directive 1663, Health Care Resources (HCR) Contracting – Buying – Title 38 U.S.C. 8153, dated May 10, 2018.

(2) Conducting and coordinating reviews with appropriate VHA program offices including NSO and incorporating all changes or modifications required in the sharing agreements in accordance with VA Directive 1663.

g. National Director of Surgery. The NDS is responsible for:

(1) Providing clinical and operational oversight and policy for the VA National Transplant Program (VANTP).

(2) Maintaining a database for tracking outcomes of Veterans referred for transplant.

(3) Maintaining a list of approved VATCs. This list can be found at: <u>https://vaww.nsopersonnel.med.va.gov/Maps/Transplant.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

(4) Maintaining a list of VATC transplant team members for each of the approved VATCs. This list can be found at: <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Contacts-and-Locations.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public. (5) Assessing and evaluating new transplant program requests from VA medical facilities and VISNs and providing recommendations to the Under Secretary for Health to approve, approve with contingencies, or deny. *NOTE:* For more information on CRR, see VHA Directive 1043.

(6) Establishing, maintaining, and providing oversight to the Transplant Surgical Advisory Board (SAB), including appointing its Chair and members.

(7) Managing Transplant Specific Purpose Funds (TSPF), including developing and maintaining criteria and methodologies for disbursement of these funds to VATCs to support and sustain their transplant program infrastructure and facilitate delivery of transplantation services to Veterans.

(8) Collaborating with VHA Office of Finance to periodically evaluate and maintain the Veterans Equitable Resource Allocation (VERA) price groups as related to transplantation. *NOTE:* For more information on VERA, see <u>http://vaww.arc.med.va.gov/</u>. This is an internal VA website that is not available to the public.

(9) Developing educational resources, including resources for referral coordinators at referring VA medical facilities, regarding Transplant Referral and Cost Evaluation/Reimbursement (TRACER) and transplant referral process and posting in the VANTP intranet website, <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-National-Transplant-Program.aspx</u>. *NOTE: This is an internal VA website that is not available to the public*.

(10) Maintaining and monitoring transplant referral processes in the TRACER application, <u>https://vaww.tracer.nso.med.va.gov/</u>. *NOTE:* This is an internal VA website that is not available to the public.

(11) Facilitating and providing final review and recommendation for transplant SAB reviews to the referring VA medical facility when a Veteran requests an additional opinion if initially found not eligible for a transplant by more than one VATC. **NOTE:** Using the identified transplant SAB review process is separate and distinct from the clinical appeal process identified in VHA Directive 1041(2), Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020, for a Veteran to appeal any clinical decision. Transplant SAB review process allows referring VA medical facilities to request an additional review by a panel of transplant advisory board clinical experts for Veterans who, upon second opinion, are deemed not clinically indicated for comprehensive transplantation evaluation. For additional information regarding the second opinion and transplant SAB review process, see

<u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Re-submission-Second-Center-</u> <u>Request-and-National-Transplant-SAB-Review.aspx</u>. This is an internal VA website that is not available to the public.

(12) Defining key quality indicators for transplantation care for Veterans receiving transplantation within VHA or at a community transplant center under VCCP.

h. <u>Chair, Transplant Surgical Advisory Board.</u> The Transplant SAB consists of a Chair, solid organ and stem cell transplant subject matter experts, and transplant coordinator representatives designated by the NDS. The Chair, Transplant SAB is responsible for:

(1) Ensuring the Transplant SAB is readily available to serve as subject matter experts to NSO on transplant related matters.

(2) Ensuring the members of the Transplant SAB complete SAB reviews requested by the referring VA medical facility following denial decisions from more than one VATC in TRACER and subsequently providing the NDS with recommendations regarding Transplant SAB reviews.

i. <u>Veterans Integrated Service Network Director</u>. The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer and Chief Operating Officer when barriers to compliance are identified.

(2) Overseeing corrective actions to address noncompliance at the VISN and VA medical facilities within the VISN.

(3) Ensuring that the VATC(s) within the VISN have necessary resources to sustain the transplant program infrastructure and provide high quality transplantation care to Veterans.

j. <u>Referring VA Medical Facility Director.</u> NOTE: A referring VA medical facility is a VA medical facility from which a referring health care provider or team refers a Veteran for transplantation to a VATC through TRACER and facilitates referral coordination by a physician or other clinical or non-clinical personnel designated by the referring VA medical facility Chief of Staff (CoS). The referring VA medical facility Director is responsible for:

(1) Ensuring a referral for each Veteran seeking transplant care is promptly submitted in TRACER for a member of the VATC transplant team to review and determine clinical indication for further comprehensive transplant evaluation. **NOTE:** For more information on stable and emergency patient transplant referrals, see <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-Process.aspx</u>. This is an internal VA website that is not available to the public.

(2) Ensuring referring VA medical facility providers submit the VA Central Office (VACO) Transplant Referral template in TRACER to share required clinical information about the Veteran unless the referring VA medical facility provider determines a clinical reason to bypass this process (e.g., emergency referrals). *NOTE:* For more information on the VACO Transplant Referral template, see

<u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-</u> <u>Process.aspx</u>. This is an internal VA website that is not available to the public. (3) Ensuring referring VA medical facility health care providers adhere to VA's transplant referral process, which can be found at https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-Process.aspx. NOTE: This is an internal VA website that is not available to the public.

(4) Ensuring requests made by the VATC transplant team for additional testing of the Veteran are promptly completed in coordination with the referring VA medical facility health care provider.

(5) Ensuring Veterans are educated on dual listing. **NOTE:** After being placed on the Organ Procurement and Transplantation Network (OPTN) waitlist for a solid organ transplant at a community transplant center, the Veteran may request to be dual listed at a VATC or an affiliate transplant center. For more information about dual listing at two transplant centers, see the "How to Dual List" tutorial located at: <u>https://vaww.tracer.nso.med.va.gov/</u>. This is an internal VA website that is not available to the public.

(6) Ensuring the Veteran receiving transplant care at a VATC and their support person are reimbursed for all authorized transplant-related round-trip transportation costs, including those related to pre-transplant evaluations, transplant episode of care, and post-transplant follow-up. *NOTE:* For more information, see VHA Transplant Travel Procedure Guide,

<u>https://dvagov.sharepoint.com/:b:/r/sites/VHANSO/SiteAssets/Transplant_Travel_Proced</u> <u>ure_Guide.pdf?csf=1&web=1&e=sBerH8</u>. This is an internal VA website that is not available to the public.

(7) When applicable, ensuring the live donor receiving care associated with solid organ, part of an organ, or stem cell donation at a VATC and their support person are reimbursed for all donation-related round-trip transportation and temporary lodging costs, in accordance with 38 C.F.R. § 17.395, which uses 38 C.F.R. § 70.30 rates but excludes the beneficiary travel deduction requirement. These costs include those incurred by the live donor in relation to receipt of pre-donation screening, evaluation, donation episode of care, and post-donation follow-up, as described in 38 C.F.R. § 17.395.

(8) Ensuring for Veterans eligible (38 C.F.R. § 17.4020(d)) for and electing to receive transplant care at a community transplant center through VCCP that the referring VA medical facility is responsible for overseeing that the care and services are provided per the terms of authorization and for following community care transplant referral process as described in the IVC Community Care Field Guidebook, found here: https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/SitePages/FGB.aspx **NOTE:** This is an internal VA website that is not available to the public. This includes notifying the VATC that initially reviewed the Veteran of the need to resume posttransplant care and follow-up if needed. OPTN policy requires the transplant center performing the live donor procedure to clinically follow the live donor for 2 years. For more information on follow-up requirements, see https://optn.transplant.hrsa.gov/policies-bylaws/policies/. (9) Ensuring all referral coordinators, as identified by the referring VA medical facility CoS or designee and defined in the TRACER VAMC Referral Coordinator Notification Group, are trained using the comprehensive educational resources and tools provided by NSO, found here:

<u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Policy_Resources.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public. For more information on training, see paragraph 3.

(10) Collaborating with the VATC medical facility Director to ensure registration of potential live donors as Veteran collaterals in the Enrollment & Eligibility System to facilitate live donor screening, evaluation, and organ donation care and services. **NOTE:** *Multiple potential live donors can be registered as collaterals and undergo initial screening simultaneously to facilitate determination of eligibility for organ or stem cell donation. Potential live donors deemed eligible for comprehensive donor evaluation will remain in the Enrollment & Eligibility System as the Veteran's collaterals. For specific details regarding simultaneous registration of multiple collaterals, refer to:* <u>https://vaww.vrm.km.va.gov/system/templates/selfservice/va_kanew/help/agent/locale/en_US/portal/55440000001046/content/554400000195651/VAMC-Enroll-Elig-VES-Non-Veteran-Registration-JA?query=Non%20Veteran%20registration. This is an internal VA website that is not available to the public. This administrative ability already exists and allows for simultaneous registration of multiple collaterals.</u>

k. **VA Transplant Center Medical Facility Director.** The VATC medical facility Director is responsible for:

(1) Providing oversight to all VATC staff to ensure VATC medical facility compliance with this directive and taking necessary corrective action when non-compliance is identified.

(2) Ensuring that each VATC maintains the necessary complexity infrastructure (e.g., appropriate staffing and Level 1 Intensive Care Unit designation) required to provide transplant services for which the VATC is approved and immediately notifying NSO if the VATC is not able to provide this infrastructure.

(3) Ensuring referring VA medical facilities have 24-hour, 7-day-a-week access to approved transplant care and services as identified on the NSO website, https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-National-Transplant-Program.aspx, including but not limited to telephone access to a member of the VATC transplant team. *NOTE: This is an internal VA website that is not available to the public.*

(4) Determining members of the VATC transplant team. **NOTE:** The VATC medical facility Director can delegate this responsibility as they see fit.

(5) Ensuring the VATC transplant team provides the NDS with a current list of team members for each VA Transplant Program (TP) located at the VATC.

(6) Ensuring appropriate travel and temporary lodging arrangements are available for Veterans receiving care at a VATC, along with their support person and their matched live donor and the live donor's support person, when applicable, consistent with the terms of 38 U.S.C. § 1788, as implemented by 38 C.F.R. § 17.395. **NOTE:** For Veterans, see further information on temporary lodging per VHA Directive 1107, Department of Veterans Affairs Fisher Houses and Other Temporary Lodging, dated October 19, 2023.

(7) Ensuring medical care of the Veteran is coordinated when transfer to an alternate VATC is requested or dictated by clinical circumstances and consented-to by the Veteran. **NOTE:** See VHA Directive 1094(1), Inter-facility Transfer Policy, dated January 11, 2017.

(8) Ensuring the VATC transplant team members document clinical and workload information in TRACER upon completion of the clinical or workload task.

(9) Ensuring the VATC transplant team reviews stable and emergency patient transplant referrals in TRACER and provides a recommendation on appropriate action.

(10) Ensuring live donor transplantation is facilitated upon identification of a donor match.

(11) Ensuring VATCs with an in-house kidney transplant program actively participate in a kidney paired donation (KPD) program.

(12) Ensuring the VATC procuring a solid organ from a live donor provides donor screening, evaluation, organ donation procedures, and post-donation follow-up for the live donor.

(13) Collaborating with the referring VA medical facility Director to ensure registration of potential live donors as Veteran collaterals in the Enrollment & Eligibility System to facilitate live donor screening, evaluation, and organ donation care and services. **NOTE:** *Multiple potential live donors can be registered as collaterals and undergo initial screening simultaneously to facilitate determination of eligibility for organ or stem cell donation. Potential live donors deemed eligible for comprehensive donor evaluation will remain in the Enrollment & Eligibility System as the Veteran's collaterals. For specific details regarding simultaneous registration of multiple collaterals, refer to:* <u>https://vaww.vrm.km.va.gov/system/templates/selfservice/va_kanew/help/agent/locale/en-US/portal/55440000001046/content/554400000195651/VAMC-Enroll-Elig-VES-Non-Veteran-Registration-JA?query=Non%20Veteran%20registration. This is an internal VA website that is not available to the public. This administrative ability already exists and allows for simultaneous registration of multiple collaterals.</u>

(14) Ensuring the VATC complies with OPTN bylaws and policies including reporting of required data to the Scientific Registry of Transplant Recipients (SRTR) and adhering to OPTN follow-up data requirements. *NOTE:* OPTN policies are available online at <u>https://optn.transplant.hrsa.gov/governance/policies/</u>.

(15) Ensuring Veterans deemed eligible for transplantation are appropriately included in the national OPTN organ waitlist and clinically managed while on the waitlist.

(16) Ensuring Veterans deemed eligible for transplantation are educated on their options to be dual-listed for transplantation at more than one transplant program at two VATCs, or one VATC and one community transplant center, or two community transplant centers. **NOTE:** Dual-listing with two community transplant centers is not routinely authorized by VA. In general, dual-listing transplant centers should be located in different geographies or donor service areas to assure access to different donor populations. Refer to:

https://dvagov.sharepoint.com/sites/VHANSO/SiteAssets/IVC%20Community%20Care% 20Transplant%20Guidance_CLEAN_FINALv3_08182022_508.pdf?cid=4a89e038-6507-470b-b04c-ebf29148419a. This is an internal VA website that is not available to the public.

(17) Ensuring appropriate internal allocation of TSPF, disbursed by NSO to support and sustain the VA medical facility's transplant program(s).

(18) Ensuring that fiscal processes for affiliated VATPs are compliant with VA Directive 1663.

I. <u>VA Transplant Center Medical Facility Chief of Staff and Associate Director of</u> <u>Patient Care Services.</u> The VATC medical facility CoS and Associate Director of Patient Care Services (ADPCS) are responsible for:

(1) Assisting the VATC medical facility Director in fulfilling the responsibilities of this directive.

(2) Ensuring the VATC transplant team has sufficient resources (e.g., medical equipment, trained personnel, operating space) to provide complete and competent transplant care to the Veteran, live donor, and their respective support persons, including the prompt addressing of any issues, when identified.

(3) Acting as the liaison between the VATC transplant team and the VATC medical facility Director.

m. <u>Referring VA Medical Facility Chief of Staff and Associate Director of Patient</u> <u>Care Services.</u> The referring VA medical facility CoS and ADPCS are responsible for:

(1) Assisting the referring VA medical facility Director in fulfilling the responsibilities of this directive.

(2) Ensuring the referring VA medical facility health care provider has sufficient resources (e.g., medical equipment, trained personnel, operating space) to facilitate a complete and comprehensive transplant referral and related care for Veterans, including coordination of necessary transfer of the Veteran to a transplant center (VA or community), their support person, and, if applicable, their matched live donor receiving care associated with organ or stem cell donation and the live donor's support person.

(3) Reviewing the decisions of the Veteran's referring VA medical facility health care providers to facilitate medically necessary transplantation care for the Veteran within VA, in the community, or both (dual-listing) and ensure well-informed, clinically appropriate decisions are made.

n. <u>VA Transplant Center Transplant Team.</u> The VATC transplant team consists of transplant physicians, transplant surgeons, transplant coordinators, transplant nurses, clinical pharmacist practitioners, administrative personnel, and physician reviewers, and is determined by the VATC medical facility Director based on OPTN transplant center staffing requirements. The VATC transplant team is responsible for:

(1) Reviewing referrals in TRACER submitted by the referring VA medical facility health care provider and making a recommendation on appropriate action. **NOTE:** For more information on TRACER submissions, see <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-</u> Process.aspx.This is an internal VA website that is not available to the public.

(2) Designating at least one VATC transplant team member to be available 24 hours, 7 days a week to immediately answer calls from referring VA medical facilities regarding transplant related issues, including initiating emergency patient transplant referrals and recommending appropriate action to the referring VA medical facility health care provider. **NOTE:** For more information on emergency patient transplant referrals, see <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-</u> <u>Process.aspx</u>. This is an internal VA website that is not available to the public.

(3) Supporting the referring VA medical facility health care provider to ensure complete medical transfer of the Veteran to the VATC when transfer of a Veteran to a VATC is dictated by clinical circumstances.

(4) Providing the NDS with a current list of team members for each transplant program located at the VATC.

(5) Notifying the VATC medical facility CoS when issues arise impeding, or potentially impeding, provision of complete and competent transplant care and services to the Veteran, live donor, or their respective support person.

(6) Facilitating and performing clinically indicated comprehensive transplant evaluations for Veterans to determine transplant candidacy.

(7) Listing Veterans deemed eligible for transplantation on the national OPTN organ waitlist and facilitating ongoing clinical management of waitlisted Veterans.

(8) Facilitating transplantation procedures when an organ is identified and available for transplantation, including live donor transplantation and post-transplantation care.

(9) Facilitating live donor screening, evaluation, organ, or stem cell donation procedures and follow-up care for live donors.

(10) Documenting clinical and workload information in TRACER upon completion of the clinical or workload task.

(11) Educating eligible Veterans on paired kidney exchange programs and actively participating in at least one paired kidney exchange program when appropriate.

(12) Reporting required data to SRTR and adhering to the OPTN follow-up data reporting requirements. *NOTE:* OPTN policies are available online at <u>https://optn.transplant.hrsa.gov/governance/policies/</u>.

o. <u>Referring VA Medical Facility Health Care Provider</u>. The referring VA medical facility health care provider makes the clinical decision to refer a Veteran for transplantation consideration. The referring VA medical facility health care provider is responsible for:

(1) Submitting stable and emergency patient transplant referrals in TRACER along with all necessary documents, including the VACO Transplant Referral template, to assist the VATC in accurately determining a Veteran's clinical indication for comprehensive transplant evaluation and subsequent eligibility for transplantation. Emergency transplant referral process includes a phone discussion with the VATC transplant team to determine a plan of care for the Veteran prior to referral submission in TRACER. **NOTE:** For more information on stable and emergency transplant referral process, VATC contract information, and the VACO Transplant Referral template, see https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Emergency-Transplant-Referral-Process.aspx. This is an internal VA website and is not available to the public.

(2) Coordinating with the VATC transplant team to ensure complete medical transfer of the Veteran to the appropriate VATC when transfer of a Veteran to a VATC is dictated by clinical circumstances.

(3) Ensuring appropriate and prompt action is taken upon receiving a recommendation or a request for additional information from the VATC transplant team regarding the stable or emergency patient transplant referral, in coordination with the referring VA medical facility Director.

3. TRAINING

a. There are no formal training requirements associated with this directive. NSO provides information, training resources, and tools to support VATC transplant team members' and VA medical facility referral coordinators' education and knowledge related to TRACER transplant referral processes. This includes:

(1) How to use TRACER.

(2) The Veteran's role in the transplant process and how to communicate this to the Veteran.

b. The comprehensive educational resources and tools can be found on the NSO intranet site (see "Guidelines and Resources" at

https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Policy_Resources.aspx). **NOTE:** This is an internal VA website that is not available to the public.

c. Additional educational resources include the Training Management System (TMS) courses listed below. **NOTE:** It is recommended that all staff involved in the transplant process also review the resources and tools provided by NSO listed below and on the NSO SharePoint.

(1) VA Transplant Referral Process Bone Marrow, TMS Curriculum ID # 38786.

(2) VA Transplant Referral Process – Heart, TMS Curriculum ID # 39317.

(3) VA Transplant Referral Process – Liver, TMS Curriculum ID # 39624.

(4) VA Transplant Referral Process – Kidney Transplant, TMS Curriculum ID # 38916.

(5) VA Transplant Referral Process – Lungs, TMS Curriculum ID # 39019.

(6) VA Transplant Referral Process (TRACER), TMS Curriculum ID # 38259.

4. BACKGROUND

a. The National Organ Transplant Act of 1984 (P.L. 98-507) established OPTN as the national organ matching and sharing system in the United States (U.S.). The Act charged the Secretary of Health and Human Services (HHS) with oversight of this system and called for OPTN to be operated by a private, non-profit organization under Federal contract (currently the United Network for Organ Sharing (UNOS)). OPTN policies govern the operation of all U.S. transplant centers and organ procurement organizations, including VATCs.

b. All transplant centers in the U.S. must be independent members of OPTN and report organ-specific data to OPTN. Analyses of outcomes data are published by SRTR and are publicly available for all transplant programs in the U.S. Although VATPs are not Medicare participants, VA voluntarily complies with HHS and OPTN requirements and policies to the extent feasible and allowed by law to enhance and maintain the VANTP. The VANTP has been resourced over decades to provide timely, high-quality, and lifelong transplant care and treatment to the Veteran population. Per OPTN guidelines, each member program is required to establish program-specific criteria and processes to determine transplant candidacy.

c. The Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129) created the C. W. Bill Young Cell Transplantation Program, which operates a system for identifying, matching, and facilitating the distribution of bone marrow and donated umbilical cord blood to suitable matched candidates and establishes an outcomes database for the purpose of evaluating patient outcomes for stem cell transplant programs. Under an HHS contract, the Center for International Blood and Marrow Transplant Research (CIBMTR)

operates the Stem Cell Therapeutic Outcomes Database (SCTOD). VHA voluntarily complies with HHS and CIBMTR requirements and policies to the extent feasible and allowed by law by reporting required data on allogeneic stem cell transplants. VHA does not provide stem cell transplant data for CIBMTR research purposes.

d. Consistent with VHA's authority to provide complete medical and hospital services for the treatment of eligible Veterans, NSO is responsible for clinical and operational oversight and policy related to the VANTP.

e. VHA transplantation care and services are facilitated through in-house VATCs and integrated affiliated VATCs.

(1) <u>In-House VA Transplant Centers.</u> In-house VATCs are independent members of OPTN and provide all components of transplantation care on-site to include TRACER referral reviews, comprehensive transplant evaluations, listing of Veterans eligible for transplant, transplantation procedures, and post-transplantation care.

(2) Affiliate VA Transplant Centers. Affiliate VA Transplant Centers are those VA medical facilities that are authorized to oversee transplantation care through an integration of VA direct care with services provided by an academic affiliate. Affiliation agreements govern the relationships of VA with local medical centers and with academic institutions that offer clinical training programs (https://www.va.gov/oaa/affiliationagreements.asp#:~:text=Affiliation%20Agreements%20govern%20the%20relationship% 20between%20the%20U.S.,and%20academic%20institutions%20that%20offer%20clinic al%20training%20programs). Integrated affiliate VATCs enter into Health Care Resources (HCR) contracts with transplant centers at affiliates to provide integrated transplant care to VA patients. Typically, these affiliate transplant centers waitlist Veterans and perform transplantation procedures at the affiliate while VATCs provide care to Veterans pre- and post-transplantation. Affiliate VATCs work closely with their affiliates' transplant centers to ensure transplant care is timely, coordinated, integrated, and clinically appropriate. Care provided by affiliates' transplant centers is distinct from VA direct-provided transplant care, despite the close and often long-standing integrated working relationship between the parties and the fact that some affiliate staff may be trainees or providers who also work at the VA facility pursuant to separate schedules and employment terms. Affiliates' transplant centers must be members of OPTN in good standing, and they retain authority and responsibility for care they provide to Veterans. Responsibilities of the affiliate transplant center and the authorized VA affiliate transplant center are formally defined through HCR contracts, which are distinct and separate from Community Care Network (CCN) contracts. NOTE: Transplant care furnished by an Affiliate VA Transplant Center occurs in the community, but it is not used in the same context as VHA-common references to "community care," as that term mainly references community care purchased care through the VCCP network and is pursuant to the rules and limitations of that program.

f. In 2013, NSO implemented TRACER, a VHA intranet-based referral system that facilitates the transplant referral of a Veteran from a referring VA medical facility to a VATC. In 2015, the TeleTransplant Operations Manual was published to provide guidance to VATCs and referring VA medical facilities in establishing a telehealth platform for care and treatment of the Veteran. **NOTE:** TRACER and the TeleTransplant Operations Manual can be accessed at <u>https://vaww.tracer.nso.med.va.gov/</u> and <u>https://dvagov.sharepoint.com/:b:/r/sites/VHANSO/SiteAssets/TeleTransplant_Ops_Manual_Supplement_10-2016.pdf?csf=1&web=1&e=p3w2gn</u>, respectively. These are internal VA websites that are not available to the public.

g. When a Veteran is eligible for a transplant procedure based on VATC criteria, VA may provide for the organ or stem cell donation from a live donor, regardless of whether the live donor is eligible for VA health care. Subject to the availability of appropriations for this purpose, VA is required to provide the live donor with medical and non-medical care and services required for and associated with organ or stem cell donation, as described in 38 C.F.R. § 17.395. Additionally, VA may provide covered services to a live donor (including those required before and after conducting the organ or stem cell donation procedure) through an affiliate transplant center or VCCP.

5. DEFINITIONS

a. <u>Allogeneic Stem Cell Transplant.</u> Allogeneic stem cell transplant is a type of transplantation that requires the transfer of stem cells from a matched related donor (i.e., a family member), a matched unrelated donor, or a bank for umbilical cord blood.

b. <u>Dual Listing.</u> Dual listing is the process of including a Veteran on the waitlist at two different transplant centers to receive a solid organ transplant. The transplant centers may be at: (1) two VATCs including affiliate transplant centers, (2) a VATC including an affiliate transplant center and an authorized community transplant center (3) at two authorized community transplant centers. Dual listing within the same OPTN region or at transplant programs with significant geographic overlap of donor referral sources is not advised. VHA IVC manages the CCN contract, which includes selection of any community transplant center contracted under the VCCP and who is part of the CCN. **NOTE:** Dual listing the Veteran at two community transplant centers may not be routinely authorized and can only be considered if VATCs are unable to provide the required transplant care to the Veteran. Listing a Veteran at more than one transplant center is allowed under OPTN policy, which can be found at

<u>https://optn.transplant.hrsa.gov/governance/policies/</u> and may or may not shorten the wait time for transplantation. TRACER supports dual-OPTN listing at two VATCs, as described. The OPTN policy for waitlisting or dual listing does not apply to stem cell transplants.

c. <u>Kidney Paired Donation</u>. KPD is the voluntary process by which two or more incompatible live donor and transplant recipient pairs exchange partners to achieve compatible donation matches for the transplant recipients. KPD provides an option to transplant recipients who are not medically compatible with their initial prospective live donor.

d. <u>Live Donor.</u> A live donor is an individual who is medically suitable for donation (per VA and OPTN policies and procedures for live donor approval) and a compatible match to an identified Veteran transplant candidate (Veteran recipient) and who voluntarily consents to undergo elective removal of one solid organ, a part of a solid organ, or stem cells in connection with the Veteran recipient's transplant procedure. Live donors can be Veterans or non-Veterans.

e. <u>Live Donor Follow-up.</u> Live donor follow-up is the care provided to live donors after transplantation for a period not less than that which the Organ Procurement and Transplantation Network prescribes or recommends or for a period of 2 years, whichever is greater (e.g., collecting clinically relevant post-donation live donor data, conducting recommended clinical laboratory tests and evaluations, and providing direct care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure, for example, an incisional hernia). *NOTE:* VATCs must adhere to OPTN follow-up requirements for live donors. OPTN policy applies to solid organ transplants only. Current OPTN policy can be found at https://optn.transplant.hrsa.gov/governance/policies/. Live donor follow-up care for stem cell donors is clinically minimal as compared to solid organ donors and is determined independently by VATCs approved to perform stem cell transplantation.

f. <u>Solid Organ Transplantation</u>. Solid organ transplantation is the process of transferring a whole or partial solid organ to a recipient for therapeutic purposes. Solid organ transplantation includes, but is not limited to, heart, kidney, liver, and lung transplantation and combinations thereof.

g. <u>Stem Cell Transplant.</u> Stem cell transplant is the process of transferring a source of hematopoietic stem cells to a recipient for therapeutic purposes and includes stem cells derived from patient's peripheral blood cells, donor's bone marrow, or peripheral blood cells or umbilical stem cells.

h. <u>Support Person.</u> A support person is an individual who accompanies the Veteran recipient or live donor to medical appointments and assists in the care and personal support of the Veteran recipient or live donor.

i. <u>Transplant Referral and Cost Evaluation/Reimbursement.</u> TRACER is a VHA intranet-based referral portal that facilitates a uniform, standardized transplant referral process for a Veteran from a referring VA medical facility to a VATC. The TRACER system also monitors data associated with the transplant referral process, captures transplant related workload entry by VATCs, and facilitates disbursement of TSPFs to VATCs. *NOTE:* TRACER can be accessed at <u>https://vaww.tracer.nso.med.va.gov/</u>. This is an internal VA website that is not available to the public.

j. <u>Transplant Specific Purpose Funds.</u> TSPF are funds allocated by VHA for disbursement by NSO to VISNs, VA medical facilities, or to certain VHA programs that are restricted for use for a specific authorized purpose. Availability of these funds are based upon VHA leadership funding allocation. For the VANTP, TSPF are disbursed by NSO to VATCs and can be used to support transplant services and program

infrastructure. **NOTE:** Determination of internal allocation within VATC is at the discretion of the VA medical facility Director.

k. <u>VA National Transplant Program.</u> The VANTP is the network of VHA-approved VATCs that provide one or more solid organ or stem cell transplant services to eligible Veterans across VA.

I. <u>VA Transplant Center.</u> A VATC is a VA medical facility approved by the Under Secretary for Health to provide one or more solid organ or stem cell transplant services to eligible Veterans across VA.

m. <u>VA Transplant Program.</u> A VATP is a solid organ or stem cell transplant service approved by the Under Secretary for Health at a VATC that is a part of the VANTP.

6. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

7. REFERENCES

a. P.L. 98-507.

b. P.L. 109-129.

c. 38 U.S.C. §§ 1703(I), 1710, 1788, 7301(b), 8153.

d. 38 C.F.R. part 70 and §§ 17.38, 17.395, 70.30, 70.31, 17.4020(d).

e. VA Directive 1663, Health Care Resources (HCR) Contracting – Buying, Title 38 U.S.C. 8153, dated May 10, 2018.

f. VHA Directive 1041(2), Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020.

g. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.

h. VHA Directive 1094(1), Inter-facility Transfer Policy, dated January 11, 2017.

i. VHA Directive 1107, Department of Veterans Affairs Fisher Houses and Other Temporary Lodging, dated October 19, 2023.

j. National Surgery Office (NSO) Policy Resources. <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Policy_Resources.aspx</u>. *NOTE: This is an internal VA website that is not available to the public.* k. National Surgery Office (NSO) Re-Submission, Second Center Request, and transplant SAB review Process,

https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Re-submission-Second-Center-Request-and-National-Transplant-SAB-Review.aspx. **NOTE:** This is an internal VA website that is not available to the public.

I. National Surgery Office (NSO) Transplant Referral Process, <u>https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Referral-</u> <u>Process.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

m. VHA. Allocation Resource Center. 2021: <u>http://vaww.arc.med.va.gov/</u>. **NOTE:** This is an internal VA website that is not available to the public.

n. VHA. Emergency Transplant Referral Process. https://dvagov.sharepoint.com/sites/VHANSO/SitePages/Emergency-Transplant-<u>Referral-Process.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

o. VHA. IVC Community Care Field Guidebook. <u>https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/SitePages/FGB.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

p. VHA. IVC Transplant Referral, Comprehensive Evaluation, & Eligibility Determination.

https://dvagov.sharepoint.com/sites/VHANSO/SiteAssets/IVC%20Community%20Care% 20Transplant%20Guidance_CLEAN_FINALv3_08182022_508.pdf?cid=4a89e038-6507-470b-b04c-ebf29148419a. **NOTE:** This is an internal VA website that is not available to the public.

q. VHA. Monitoring Referrals in TRACER. <u>https://vaww.tracer.nso.med.va.gov/</u>. **NOTE:** This is an internal VA website that is not available to the public.

r. VHA. National Transplant Program.

https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-National-Transplant-Program.aspx. **NOTE:** This is an internal VA website that is not available to the public.

s. VHA. Office of Academic Affiliations Affiliate Resources.

https://www.va.gov/oaa/affiliation-

agreements.asp#:~:text=Affiliation%20Agreements%20govern%20the%20relationship% 20between%20the%20U.S.,and%20academic%20institutions%20that%20offer%20clinic al%20training%20programs.

t. VHA. Specialty Surgical Programs. <u>https://vaww.nsopersonnel.med.va.gov/Maps/Transplant.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

u. VHA. TeleTransplant Specialty Operations Manual. https://dvagov.sharepoint.com/:b:/r/sites/VHANSO/SiteAssets/TeleTransplant_Ops_Man <u>ual_Supplement_10-2016.pdf?csf=1&web=1&e=p3w2gn</u>. **NOTE:** This is an internal VA website that is not available to the public.

v. VHA. Transplant Travel Procedure Guide. <u>https://dvagov.sharepoint.com/:b:/r/sites/VHANSO/SiteAssets/Transplant_Travel_Proced</u> ure_Guide.pdf?csf=1&web=1&e=sBerH8. **NOTE:** This is an internal VA website that is

ure_Guide.pdf?csf=1&web=1&e=sBerH8. **NOTE:** This is an internal VA website that is not available to the public.

w. VHA. VA Transplant Contacts and Locations. https://dvagov.sharepoint.com/sites/VHANSO/SitePages/VA-Transplant-Contacts-and-Locations.aspx. **NOTE:** This is an internal VA website that is not available to the public.

x. OPTN Policies. 2021. https://optn.transplant.hrsa.gov/governance/policies/.

y. OPTN Policy & Guidance. <u>https://optn.transplant.hrsa.gov/professionals/by-topic/living-donation/</u>.