

May 21, 2021

The Honorable Denis McDonough  
Secretary  
U.S. Department of Veterans Affairs  
810 Vermont Avenue NW  
Washington, DC 20420

**RE: [38 CFR Part 17] Transplant Procedures with Live Donors and Related Care Services,  
Department of Veterans Affairs**

Dear Secretary McDonough,

The Organ Procurement Transplantation Network (OPTN) is pleased to submit comments in response to the proposed amendments to 38 CFR Part 17, *Transplant Procedures with Live Donors and Related Care Services*. The OPTN is the nation's organ donation and transplantation network and is made up of over 350 clinical, professional, patient and donor volunteers. The OPTN has carefully reviewed the final rule as posted on March 24, 2021. The OPTN supports the goals of the rule to remove obstacles to donating a solid organ, part of a solid organ, or bone marrow and the VA's commitment to provide eligible veterans timely, high quality care and treatment.

In response to the proposed modifications, the OPTN wishes to reiterate existing requirements relating to living donor organ recovery. As referenced in the published document:

*VA transplant programs are members of the Organ Procurement and Transplantation Network (OPTN) established by section 372 of Public Law (Pub. L.) 98-507 (1984), as amended, and codified at [42 U.S.C. 274](#). The regulatory scheme in part 121 of title 42, Code of Federal Regulations (CFR) governs OPTN operations, and the provisions of section 373 of Public Law 98-507 (codified at [42 U.S.C. 274a](#)) require the operation of a Scientific Registry ("Registry") to allow for an ongoing evaluation of the scientific and clinical status of solid organ transplantation. Approved transplant programs must thus report specified data to the Registry. Admission to and membership in the OPTN is governed by [42 CFR 121.3](#); the provisions of [42 CFR 121.9](#) establish the requirements for OPTN-designated transplant programs and expressly include VA transplant programs. *Id.* at § 121.9(a)(3). The OPTN Board of Directors is charged with developing policies that are enforceable once approved by the Secretary of Health and Human Services. *Id.* at § 121.4. Compliance with OPTN rules and policies by designated transplant programs is required by [42 CFR 121.10](#). VA designated transplant programs comply with approved and applicable OPTN by-laws and policies. In addition, clinical standards of care and patient safety standards apply to VA's delivery of care, including transplant care.*

OPTN Bylaws, Appendix E.6 for Kidney and Appendix F.8 for Liver Transplant Programs, define requirements for transplant programs that recover organs for transplant from living donors, even if the recovery occurs in a hospital separate from the transplanting hospital.<sup>1</sup>

In the proposed rule, paragraph (e)(1)(i) would provide for VA to enter into agreements with non-VA facilities for them to provide a surgical procedure and care and services described in paragraph (c) of this section.

*(c) Hospital care and medical services...*

*(2) During removal of a solid organ, part of a solid organ, or bone marrow, VemA will provide the surgical procedure to remove a solid organ, part of a solid organ, or bone marrow from the living donor whose solid organ, part of a solid organ, or bone marrow will be transplanted into an intended recipient.*

OPTN requirements specify that transplant programs only use living donor organs recovered from OPTN approved living donor recovery hospitals. As referenced in the rule, VA transplant programs are members of the OPTN, when VA enters into agreements with non-VA facilities, it is important to ensure that these non-VA facilities are approved for the recovery of organs from living donors if the recovery will occur in these non-VA facilities. The transplantation of an organ recovered from a living donor in a hospital that is not OPTN approved is considered a violation of OPTN obligations as well as a patient safety concern. Considering the proposed rule refers to other OPTN requirements, including OPTN policies for living donor evaluation and follow up reporting, but was silent on minimum requirements for living donor recovery hospitals, we wished to express the importance of making this clear during final rulemaking.

Finally, the proposed rule should be sure to be explicit about requirements for outcomes reporting, compliance monitoring, and other considerations between bone marrow and solid organ transplant, given their distinct contractual relationships with the federal government.

Again, we wish to thank the Veterans Affairs Department for this important and critical change that stands to expand access to living donations for those that have served our nation. We are pleased to serve as a resource as needed.

We welcome the opportunity to discuss further with you if needed.

Sincerely,



David Mulligan, MD, FACS  
President, OPTN Board of Directors

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<sup>1</sup> "OPTN Bylaws." Organ Procurement and Transplantation Network. 7 December 2020.  
<https://optn.transplant.hrsa.gov/governance/bylaws>.