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American Society of Transplant Surgeons®

April 22, 2019

Joseph Duran
Director, Office of Community Care (10D)
Veterans Health Administration
Department of Veterans Affairs
Pfarmigan at Cherry Creek
Denver, CO 80209

RE: RIN 2900-AQ46, Veterans Community Care Program.

Dear Mr. Duran:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on the Proposed Rule published in the Federal Register on April 5, 2019 (the Proposed Rule) implementing those provisions of Section 101 of the MISSION Act of 2018 that specifically authorize transplantation in a non-VA Transplant Center outside a resident's Organ Procurement Transplantation Network (OPTN) region under specified circumstances (53 USC §1703(I); hereafter ("§ 1703(I)"). ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS believes that veterans should have the option to choose to be transplanted in non-VA Transplant Centers, and we are pleased that the VA has taken steps to expand access to transplantation outside of a veteran's Organ Procurement and Transplantation Network (OPTN) region, as set forth in § 1703(I).

Unfortunately, we believe that the Proposed Rule and related preamble language is somewhat confusing. For this reason, we urge the VA to make it clear in the Final Rule that:

- It is up to the veteran to decide whether to obtain a transplant from a VA Transplant Center (VATC) or a non-VA Transplant Center located within the veteran's OPTN region. We note that there are only 11 OPTN regions in the country, and, accordingly, the VA regions are quite broad. As a result, it appears likely that one or more non-VA Transplant Centers will be located within the OPTN region for most veterans, and that most veterans therefore will have a choice between a VA and a non-VA Transplant Center.

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- While special rules are applicable to veterans who have a medically compelling reason to obtain transplantation outside of the OPTN region, it was Congress' intent for these rules to "improve" access to transplantation. (We note that the applicable provision of the governing statute is entitled "Authority for Improved Access."). Contrary to the preamble to the Proposed Rule, it appears that this option is to be made available for all "covered" veterans who have a medically compelling reason to obtain a transplant outside of the OPTN region, regardless of whether or not there is VA Transplant Center within that region: The statute only requires a veteran to be covered (or eligible for coverage) by the VA health system for this option to be available to him or her: There is no requirement for any other eligibility requirement to be met.

Also, while the statute does appear to contemplate some role for the Secretary in determining whether a veteran may be transplanted outside of his or her OPTN region, we would urge that considerable deference be given to the veteran's primary physician, who, under the statute, is specifically charged with the responsibility of determining whether there is medically compelling reason to seek transplantation outside of the OPTN region.

Finally, we request that the Final Rule include a provision that clearly sets forth the time within which the Secretary is required to make a decision on a veteran's request to be transplanted at a non-VA Transplant Center located outside of the OPTN region. We also request the inclusion of a provision that facilitates expedited decisions (or waiver of the Secretary's authority to approve an out-of-region transplant) in the case of an emergency.

We appreciate the opportunity to comment on the Proposed Rule. If you have any questions regarding our position on this issue, or if we can provide any further information, please do not hesitate to contact Jennifer Nelson-Dowdy at <mailto:jennifer.nelson-dowdy@asts.org> or (571) 447-5447.

Sincerely yours,

A handwritten signature in black ink that reads "Dixon Kaufman". The signature is written in a cursive, flowing style.

Dixon B. Kaufman, MD, PhD
President
American Society of Transplant Surgeons