American Society of Transplant Surgeons

February 14, 2012

James Bowman, MD
Medical Director
Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Room 12C-06
Rockville, MD 20857

Re: RIN 0906–AA73; Federal Register / Vol. 76, No. 242

Dear Dr. Bowman:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to respond to the above-referenced notice of proposed rulemaking (the "Proposed Rule"), which sets forth the Secretary's proposal to include vascularized composite allografts (VCAs) within the definition of "organs" in the Organ Procurement and Transplantation Network (OPTN) rules. The ASTS is comprised of over 1900 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with organ failure.

The U.S. military has made outstanding advances for the protection of our service men and women. The development of a highly protective vest has provided the ability to safely shield the thorax and abdomen, saving many lives; however, the exposure of the extremities and the head and neck result in the higher number of amputations and burns. For this reason, the recent conflicts have increased the need for limb and tissue reconstruction. The Department of Defense provides significant support for research programs for scientific advancement in this field, both in regard to VCA and prosthetic development. Similarly, the Veteran Affairs had the vision to support research programs as early as 2008 and currently provides veterans the option of hand transplantation at the Atlanta Veterans Affairs Medical Center.

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At this stage, the government is supporting research across a range of topics in an effort to learn how best to care for our wounded warriors, and in recognition of the fact that different people will require different approaches to get them to their most functional state. Research into the field of VCA is a critical component of this effort, and HRSA's proposal to classify VCA as organs for the purpose of OPTN oversight is a significant step forward in recognizing advancements in this field.

We strongly favor the inclusion of VCAs in the definition of "organs" for OPTN oversight purposes. The inclusion of VCAs (e.g. hands, arms, face) under the auspices of the OPTN will be beneficial to physicians, patients, the field, and the society at large by providing common safety standards that are consistent with the existing practice of organ transplantation. Transplantation practices have evolved over decades to deal with a number of the salient issues facing VCA researchers, and we believe that including VCAs under the authority of the OPTN (and hence under the authority of HRSA), will be beneficial to the field by ensuring that, as knowledge and expertise in this field grow, consistent and rigorous standards are all transplantation – including VCA procedures.

We particularly support the inclusion of VCAs in the definition of "organs" for OPTN purposes insofar as this will ensure that physicians will be required to perform VCA procedures at OPTN member transplant centers. The OPTN transplant center requirements will effectively ensure that VCA transplant teams provide patients with the necessary services and infrastructure required for these complex procedures.

We also believe that the transparency and rigor characteristic of OPTN policymaking processes will contribute to advancement of the field. Once the field fully matures, all transplant teams – whether engaged in the performance of VCA procedures or other organ transplants – will follow similar rules, have defined relationships with organ procurement organizations, and will produce outcomes information that is well understood by the transplant community and accessible to the public. The type of public transparency that characterizes OPTN policymaking is necessary for the field, particularly in terms of the development of an effective and balanced allocation policy designed to provide the maximum benefit to prospective patients and to society.

At the same time, it is critical to note that, due to the small number of patients and the short term outcomes reported to date, these procedures continue being considered in development**.** The advancement of the field in a scholarly, evidenced-based fashion will provide the best outcomes for VCA recipients; however, care must be taken not to overburden the field with administrative and other requirements that jeopardize the continued financial viability of research in this field.

In this regard, while we are experiencing a growth period and more centers are considering performing these procedures, it should be recognized that these surgeries are likely to be appropriate for a selected group of patients, and the long-term outcomes and the parameters for

patient selection are yet to be defined. The clinical and cost effectiveness of VCA as compared with other alternatives remains unclear, and it appears likely that, at least over the short term, VCA likely will be performed at a minority of centers and will be heavily dependent on research funding.

Under these circumstances, it is critical that the OPTN proceed cautiously in subjecting VCA procedures to potentially burdensome administrative requirements and to policies that may substantially increase the cost of VCA research. In this regard, the negative precedent set with regard to islet cell transplantation is instructive. In that case, based on the positive reported results of islet cell transplantation research, Congress mandated Medicare coverage of islet cell transplants conducted under a specified NIH research protocol. Partially as the result of this legislation, CMS mandated that pancreata acquired for use in islet cell transplantation be treated as organs for OPO cost reporting purposes. The application of CMS cost finding and allocation policies to pancreata acquired for islet cell research purposes led to a dramatic and financially unsustainable increase in the cost of such pancreata. Ironically, this cost increase made continued research in the field financially prohibitive for many centers, which subsequently discontinued their islet cell transplantation research. It is critical to ensure that the classification of VCAs as "organs" for OPTN purposes does not have a similar impact on this promising field.

In this regard, it is important to keep in mind that, while VCAs are "organs" for all of the reasons cited in the Proposed Rule, this does not mean that researchers have developed sufficient knowledge to formulate the type of comprehensive patient selection, outcomes standards, allocation and other policies that have been developed for other organs. Under these circumstances, it does not appear that knowledge in the field is sufficient for VCA to be treated identically to other organs for all OPTN purposes. We believe that the OPTN regulations should reflect this reality.

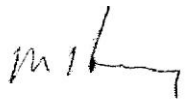
We therefore urge HRSA to provide the OPTN with the flexibility to proceed cautiously in this area, to ensure that regulatory standards do not precede clinical knowledge and do not overburden this nascent but promising field. In our view, it may be appropriate for the OPTN to proceed in stages in this arena by first establishing safety standards that (a) require all VCA procedures to be conducted only in transplant centers that are members of the OPTN; and (b) establish appropriate training and experience requirements for the transplant team. In addition, during the first phase, we would hope that the OPTN will establish basic and uniform data reporting requirements that will facilitate the eventual formation of a comprehensive data base, without imposing on VCA research the extraordinarily heavy administrative burdens associated with data reporting for other forms of organ transplantation. It is possible, if not likely, that flexibility may be necessary to assure that other OPTN policies are appropriately scaled to accommodate the fact that VCA remains in the research stage of development.

Likewise, while we firmly support the establishment of organ allocation policy for VCAs, it is unclear to us whether the research in this field is sufficiently advanced for such policies to be developed immediately or for the full OPTN national listing apparatus to be usefully applied to VCAs. The immediate inclusion of VCA in the OPTN's computer-based listings and the establishment of a national system for VCA matching requires considerable knowledge of patient selection criteria – criteria that have not yet been developed. We believe that, pending the necessary advances in research, transplant centers that are performing VCA procedures on a research basis should be able to continue to obtain the necessary allografts from their local OPOs based on individually-negotiated contractual arrangements.

We recognize that the impact of this proposed expanded definition of organs may increase participation in deceased organ donation. As an organ under development, we believe that donation of VCA should follow research parameters including a separate consent for research.

Summarizing, then, we strongly support HRSA's proposal to include VCAs in the regulatory definition of "organs" for OPTN oversight purposes, and urge the agency to include in the final regulation a provision that makes it clear that OPTN policies in this area may deviate from those established for other organs in a manner that recognizes the research status of these promising procedures. We hope that these comments are useful to HRSA in proceeding forward to advance this important field of research.

Sincerely,



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President