

# WAITLIST ZERO

## Campaign Description— HRSA FUNDING FOR LIVING DONATION

### Table of Contents

1. Executive Summary
  2. Grant Policy and Legal Background
  3. Policy Rationale and the Need for Change
  4. Path to Change
  5. Building Advocacy Capacity
- 

### Executive Summary

**The Policy:** Increasing living kidney donation is necessary to end the transplant shortage, but responsibility for living kidney donation policy has no current home in the federal government. The Health Resources and Services Administration (HRSA) oversees deceased organ donation and several programs related to living donation, but to date HRSA has been uncomfortable with supporting efforts to promote living donation. For example, it is charged with providing grants to research and increase organ donation, including living donation, but it has decided not to fund “projects that attempt to encourage living donation, increase the number of living donors or increase individuals’ readiness/willingness to pursue living donation.” In the near term, HRSA needs to change this policy of differential treatment for living donation. This can then allow a coherent living donation policy to be initiated and implemented at the federal level.

**The Reason:** HRSA justifies its reservations in promoting living donation as “because of the risks associated with any major surgical procedure,” but we find this logic misguided: living kidney transplant saves thousands of lives each year, and for many patients it is the only option to avoid dialysis. Since deceased donation can never be sufficient to end the waiting list, a policy to not increase living donation takes a transplant shortage as a given and assumes it to be an acceptable outcome. It must be changed.

**The Plan:** Patient and donor groups will send a formal letter of inquiry to HRSA on October 13<sup>th</sup> voicing support for living donation and asking HRSA to explain their own stance. Broader support for living donation will be mobilized to influence HRSA’s answer to the letter. This will include: a support letter from nonprofits and professional organizations (along with patient groups); individual letters to HRSA from transplant professionals, patients, bioethicists, and donors; lobbying of legislators by supporters; and publicity efforts centered around editorial-writing, social media, and awareness-raising.

---

## Grant Policy and Legal Background

The Health Resources and Services Administration (HRSA) is the department within the Department of Health and Human Services that administers the Organ Procurement and Transplantation Network (OPTN) contract and that is charged with providing grants to increase solid organ donation. Specifically, 42 U.S. Code §274f-1(b) indicates that “The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.” HRSA manages this program.

Despite the language above indicating support for living donation, [HRSA does not allow](#) its grants to promote solid organ donation to be used for “efforts to educate about and/or increase living donation.” Though HRSA has indicated they do not plan to award these grants in 2015, there is approximately \$6.5M annually available for HRSA grants to increase solid organ donation (p. 292, [HRSA Justification of Estimates for Appropriations Committees FY 2015](#)). These grants are distributed through three programs: Social and Behavioral Interventions to Increase Solid Organ Donation, Public Education Efforts to Increase Solid Organ Donation, and Clinical Interventions to Increase Organ Procurement with the first two programs together likely receiving 75% or more of the funding. In the last year for which records were available, living donation-related efforts were excluded from all HRSA grant funding described above.<sup>1</sup>

---

## Policy Rationale and the Need for Change

A [2012 HRSA Request for Proposal](#) justified the exclusion of measures to increase living donation “because of the risks associated with any major surgical procedure.” Since the vast majority of living donor transplants involve kidney donation, we assume the risks described are those of laparoscopic nephrectomy, which has a mortality rate of approximately three in ten thousand and significant complications for 1-2% of living kidney donors. In addition, it should also be stated that recent studies have found living kidney donors experience an increase in kidney failure in living donors estimated at 0.8% (from 0.1% had they not donated to 0.9% post-donation; by comparison the average American has a lifetime risk of kidney failure of 3.2%).

Nevertheless, we feel that the HRSA logic is misguided and contrary to the statute authorizing these grants, which explicitly intends to promote living donation. All surgery involves significant health risks. What matters is the informed consent of the donor. Studies have consistently found that fewer than 5% of all living organ donors regret

---

<sup>1</sup> Note that HRSA separately has a statutory obligation to make grants to “provid[e] for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs.” 42 USC 274f(a)(1). This program, the National Living Donor Assistance Center, is administered through a cooperative agreement between the American Society of Transplant Surgeons and the University of Michigan.

# **WAITLIST ZERO**

their choice. Refusing to acknowledge living donation as worth promoting delegitimizes the choices of the five thousand Americans each year who choose to give.

Moreover, even taking a narrow definition of a donor's welfare, giving a kidney is often in their own best interest, since donors typically have a direct stake in the well-being of their recipient. For example, a wife would likely be better off if she gave her spouse a transplant than if her recipient were on dialysis or deceased. That is what makes paternalistic skepticism toward living donation so misguided. Donors should decide for themselves, and society should honor their decision to give.

The policy also draws a false equivalence between the health risks to donors of surgery and to patients of dialysis. The chance of a patient with kidney failure surviving on dialysis for 5 years is 36%, about the same as someone diagnosed with brain cancer. Since the average wait time for a deceased-donor kidney is 4.5 years and growing, neglecting living donation consigns many such patients to death. What's worse, the patients with the least access to transplantation (living and deceased) are the indigent and people of color, so HRSA's policy disproportionately discriminates against these underprivileged groups.

American transplant policy must make a choice between treating the transplant shortage as a fact of life or as a problem demanding a solution. Without increasing living donation, there will always be a transplant shortage for kidneys. Currently, 75% of those who can donate after death do so: even if it were possible to procure transplants from every such candidate, that would only be another 3,500 kidney transplants, still leaving at least 4,000 patients to die or become too sick to transplant each year. This is unacceptable.

Government policy must promote living donation. Currently, the public does not understand the details of living donation as well as they do deceased donation. Patients and their families have no institutional support in receiving education about living donor transplant or in finding a donor. Many do not know about the option of kidney exchange (and many centers still do not participate in exchange programs). Donors are left to pay their own lost wages and childcare, and no government agency ensures follow-up care or long-term study. The federal government needs to create clear lines of responsibility for living donation and needs to house that in one agency. Guaranteeing equal treatment of living donation promotion efforts is a critical first step.

---

## **Path to Change**

This campaign will engage HRSA with living donation issues and force a reconsideration of federal policy. The campaign will raise these issues by focusing primarily on equal treatment for living donation under HRSA's §274f-1(b) grant programs and in HRSA's public statements about donations and its own performance goals.

A letter of inquiry to HRSA from patient and donor groups will be sent October 13th. This letter expresses support for living donation, inquires into HRSA's involvement, and

# **WAITLIST ZERO**

asks for a meeting before HRSA can give its answer. Our expectation is that an answer to this letter will not be immediate. This will give time for our efforts to mobilize support, persuade legislators, and advocate publicly in order to influence HRSA's answer to the inquiry. If HRSA answers quickly, these advocacy efforts will aim at modifying the answer as needed.

The initial post-letter efforts will revolve around mobilizing broader support beyond the patient organizations to individual patients and donors, transplant professionals, interested nonprofits, and professional organizations. This will lead to a letter of support from these organizations to HRSA about the necessity to promote living donation. It will also lead to a letter-writing campaign to HRSA from allied individuals.

This may be followed by a public editorial-writing and publicity-gathering campaign focused on the issue. Simultaneously, we will also gather support from legislators, focusing primarily on the relevant subcommittees with oversight over HRSA.

As needed, the campaign will then expand to educate and influence other groups who did not, sign on to the effort initially. Litigation options to enforce the "living donation" provision in the §274f-1(b) grant language will be considered. Public events of patients and donors may be attractive tactics, either in the districts of influential transplantation allies or outside the offices of HRSA itself.

---

## **Building Advocacy Capacity**

This campaign has clear, significant, and achievable goals, and it will involve a broad swathe of transplant organizations, gain media interest, and reach federal legislators. Therefore, we believe it is a great starting point for building advocacy capacity and familiarity on transplant issues concerning living donation. We hope it is the first step in a broader effort to increase living donation and that it will lead to clear lines of responsibility for living donation within the federal government and a "National Organ Transplant Act" for living donation that might include policies such as paying for donor lost wages, public education campaigns about living donation, patient education about transplantation, waitlist priority for kidney donor family members, kidney exchange promotion efforts, pilots of providing healthcare and similar benefits to donors, and using deceased organ donors to start paired kidney donation chains that end with the top person on the deceased donor waitlist. The first step to these efforts, however, focuses narrowly on treating support for living donation as equivalent to deceased donation.