

WAITLIST ZERO

HRSA Meeting Strategy Memo

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Introduction and Purpose of Memorandum

We will be meeting with the Health Resources and Services Administration (HRSA) on January 16th at 1 PM to discuss its lack of support for increasing living kidney donation. This memorandum is intended to provide an initial guide for discussion and consideration of strategic issues regarding that meeting. The conclusions drawn here are preliminary and fully open to debate and revision. Additionally, there may be important considerations that we overlooked. We hope to hear your comments and to make our coalition's meeting strategy as strong as possible through your (much-appreciated) critical feedback.

Please review this memorandum prior to our phone call on Monday, January 5th. If you have written comments to help guide the discussion, please send them to Josh Morrison at josh@waitlistzero.org. They'd be tremendously helpful. Additionally, we will be circulating a call agenda on Friday afternoon, January 2nd. Please submit any items you'd like to be on the agenda before then.

Meeting Logistics

Timing: The meeting will begin promptly at 1 PM at HRSA headquarters, which are located at 5600 Fishers Lane, Rockville, MD 20857. We will be meeting at Café 5601 at 5601 Fishers Lane at 11:45 AM and walking over to the HRSA headquarters no later than 12:30 PM. After our meeting has concluded, we will plan on debriefing for half an hour at Café 5601 or another location nearby.

Travel: For those traveling on Friday from New York, the best alternatives are the 7:17 AM Northeast Regional or the 8 PM Acela, each arriving in Union Station in Washington, DC. From Union Station, the Red Line towards Shady Grove runs to Twinbrook Metro Station. From there, HRSA headquarters (and Café 5601) is approximately a ten-minute walk.

Spokesperson and Remarks: Our expectation is that Josh Morrison of WaitList Zero will lead the meeting and after introductions, make the opening remarks. To ensure an orderly response to HRSA comments and questions, our plan had been for Josh to be responsible for directing questions and comments to appropriate respondents in our group as well as answering some of them himself. Prior to the meeting, we should discuss who has expertise in what types of questions and how the meeting should be conducted.

Strategic Decisions

Coalition Name: The working name for the coalition is The Coalition to Support Living Kidney Donation. We are very open to other suggested names, though we expect to finalize a name on our 1.5.15 phone call.

Pre-Meeting Campaign Preparation—

- ***Information to Submit to HRSA Pre-Meeting:*** We plan to submit materials to HRSA a week before the meeting to provide some background context—e.g. academic studies, our statement of principles, and a list of grants to increase living donation provided by other agencies. What materials should we provide? Providing documentation that makes our case too explicitly may run the risk of overshadowing our presentation during the meeting, but providing nothing may lead to an underinformed discussion. An additional question is whether we should prepare a powerpoint presentation to go along with our remarks.
- ***Social Media Campaign:*** To demonstrate public support for living kidney donation, we intend to conduct a social media campaign starting the Monday before the meeting and ending that Friday. A separate memo describing this campaign will be circulated the evening of January 1, 2015.
- ***Letter-Writing Campaign:*** We have been conducting a low intensity letter-writing campaign in support of living donation. So far, several dozen letters have been sent. We hope to work with each of the groups in the coalition to recruit a total of about 50-100 more letters before the meeting with significantly more following thereafter, with a goal of having sent five hundred letters by March 1st.
- ***Recruitment of Additional Ally Organizations:*** In addition to the four signatories of the Letter of Inquiry sent on October 14th, we hope to recruit other organizations to officially join the coalition, with a few hopefully joining before the meeting and the bulk joining thereafter. During our January 5th phone call, we will discuss organizations we might approach and potential leads.
- ***Media Involvement:*** To date, we have not reached out to the media to publicize our campaign, since we were not seeking coverage before the meeting. While the topic will likely not be media-ready in the immediate aftermath of the meeting, it may be a good idea to explain the campaign to media prior to January 16th. We will discuss on the upcoming phone call.
- ***Other:*** What other campaign preparation should we conduct that has not been included in this memorandum?

Meeting Goals: Our group hopes to: be persuasive to HRSA; impress them with our commitment, sophistication, and seriousness; gauge HRSA's willingness to change policy; and solicit answers to our factual questions about HRSA. It is unreasonable to expect a yes answer in this meeting, but we must decide if we have an intermediate ask that HRSA could plausibly give a yes to prior to acquiescing to our policy change requests.

Public Meeting: In particular, one intermediate ask might be a HRSA-conducted public meeting to reconsider its policy towards living kidney donation. Such an announcement would allow stakeholders whose interests are entangled with HRSA's to make a public statement on the issue. These include professional associations that receive money from HRSA's National Living Donor Assistance Center contract as well as transplant professionals involved with UNOS or the SRTR (each entity a HRSA contractor). We should decide whether we want to ask for this and, if so, if we want to make this ask in our opening remarks or do so later in the meeting.

Likely Public Meeting Formats: One precedent for such a public meeting would be the [public "listening sessions" conducted by HRSA](#) for the Ryan H. White AIDS program in 2012. Those were conducted by teleconference, though a public meeting on living donation would ideally be in-person. HRSA may likely prefer, however, to refer the issue to the [Advisory Committee on Transplantation \(ACOT\)](#), the network of appointees tasked with providing HRSA with advice on difficult transplantation decisions. To our knowledge, ACOT did not meet in 2014, and asking them to provide a recommendation may be a way of delaying and deferring a decision. Moreover, as a group of non-governmental advisors, they will not be as accountable to demonstrations of public support. On the other hand, we spoke to the Chair of ACOT, Mark Barr, in October, and he expressed private support for living donation. We are inquiring into further details about ACOT and their operations. Prior to the January 16th meeting, we should decide what our response to a suggestion of ACOT referral should be.

Our Response to Other Potential HRSA Reactions: Given that we will not be able to confer during the meeting, we should additionally game out our reply to other possible HRSA reactions and

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counteroffers. Prior to the meeting, we will also be circulating a list of potential HRSA arguments in favor of their position together with potential replies. Please suggest other HRSA responses not included below.

- *HRSA Suggests Referring Issue to UNOS:* UNOS is a HRSA subcontractor, notoriously decentralized and slow-moving, and responsible primarily for deceased donation. We believe we should strongly oppose as inappropriate any suggestion of HRSA to refer decision-making to UNOS.
- *HRSA Indicates Willingness to Support Public Education But Not For Directly Increasing Donation:* Since the purpose of our campaign is to put living donation on equal footing with deceased and lay the groundwork for policies to increase living donation, we think this does not comport with our principles and would be an unacceptable compromise.
- *HRSA Indicates the Need for Notice and Comment Rulemaking:* There does not appear to have been a regulation promulgated to establish a rule concerning living donation. Nevertheless, HRSA may wish to go through a rulemaking process if they plan on changing or reconsidering policy. This would involve announcement in the Federal Register of a notice-and-comment period and establishment of an explicit regulation. This may prolong the timeline past what we would want and may be an inferior substitute to an in-person public meeting. On the other hand, it would indicate taking our query seriously, and it would provide us an opportunity to mobilize comments during this process. We should discuss our potential reaction to this approach.

Information to Solicit at Meeting: In accepting this meeting, Robert Walsh, Director of the Division of Transplantation at HRSA expressed his interest as: “I would be happy to meet with you to hear more about the questions you raise in your letter.” Nevertheless, besides making our own case, we also wish to solicit information from HRSA concerning their policies. Below are some questions to which we would like answers. Suggestions for additional questions are appreciated.

- Why does HRSA not explicitly support efforts to increase living kidney donation?
 - How did it arrive at this policy? Whose opinion did it solicit?
 - Is there a regulation concerning living donation promulgated by HRSA?
 - What is the procedure for changing the policy?
 - What are the prospects for change?
- New grants to promote solid organ donation are not being offered in 2015 even though the FY 2015 budget allocates \$6M for them (the same as the typical year). Why are these grants not being awarded and where is the money allocated to them in the FY 2015 budget going?
 - Note that we had asked HRSA this question in early September but have not received an answer.
- How are decisions made as to what goals are included in the FY 2016 Annual Performance Report?

Expected Plan After Meeting: After the meeting, we will have a group call scheduled for the week of the 18th to discuss next steps. We anticipate continuing the pre-meeting campaigns described above and expanding to begin legislative and media outreach as well as a more public communications strategy through editorials and awareness-raising.

Meeting Agenda First Draft

- Introductions 5-10 Minutes
- Coalition Opening Remarks – 10 Minutes
- HRSA Response and Discussion – 10 Minutes
- Discussion of HRSA Policy Rationale –10 Minutes
- Discussion of HRSA Grant Program –10 Minutes
- Discussion of HRSA FY 2016 Performance Report –10 Minutes

Outline of Our Remarks to HRSA – First Draft

1. Introductions
2. Thank You for Past Work to Increase Organ Donation
3. Deceased Donation Can Never End the Kidney Shortage
4. Our Long-Term Goal: Persuade Congress to appropriate more money to HRSA for policies promoting living donation
 - a. Patient Education,
 - b. Public Education
 - c. Donor Lost Wages
 - d. Kidney Paired Donation.
5. Specific Asks to HRSA
 - a. Remove Exclusions on Living Donation from Any Future Grant Funding
 - b. Include Living Donation Metrics in FY 2016 Performance Report
 - c. Publicly Commit to Supporting Policies that Increase Living Kidney Donation
6. Concern with Donor Safety Is Not a Reason to Avoid Living Donation Efforts
7. Our Rationale for Changing the Policy
 - a. Informed Consent Is the Right Standard
 - b. Government Advocacy for Living Donation Will Not Diminish Informed Consent
 - c. Donation Is Often in Donors Self-Interest, Even Narrowly Defined
 - d. Government Already Supports Thousands of Living Donations Each Year
 - e. HRSA Obligated to Taxpayers and Patients to Pursue a Well-Founded Policy
8. HRSA Is Alone in Its Current Stance
 - a. Congress Has Indicated Clear Intent to Promote Living Donation.
 - i. The granting statute explicitly says “including living donation”
 - b. Other Agencies Support Efforts to Increase Living Donation: NIH, AHRQ, CMS
 - c. What Community or Expert Involvement Led to HRSA’s Current Stance?
 - d. Pro-Living Donation Trend
9. Description of Our Campaign
 - a. Letters of Support
 - i. Friendly in tone
 - ii. We plan to expand this and social media significantly throughout February
 - b. Nonprofit Coalition in Support of Our Campaign
 - c. Plans to Mobilize Federal Legislators
 - d. Media Coverage and Editorials
10. Tone of Campaign
 - a. We Want a Friendly and Cooperative Relationship with HRSA
 - i. Ideally, our campaign will establish stakeholder support for living donation and make the policy safe for HRSA to support
 - ii. If HRSA is criticized for this policy in the future we will support HRSA and the process that led to the change.
 - b. Prepared for a More Confrontational Approach If Necessary
 - i. Next stage after friendly letters is to solicit video messages from and media coverage of sick patients and people who’ve lost family members asking why HRSA doesn’t support this policy.
 - ii. May also explore legal remedies concerning grant funding under an arbitrary and capricious review standard given the statutory language in favor of living donation.
11. Our Commitment
 - a. Life and Death Issue for the Patients Represented by Our Coalition
 - b. Existential Issue for WaitList Zero Given Our Mission
 - c. No Matter the Timeline, We Will Continue to Push This Issue
12. Conclusion
 - a. We Don’t Expect a Yes Now, But Hopefully Today We Can Figure Out a Path Forward that Works Both for HRSA and Our Coalition