August 19, 2014

Mary K. Wakefield, PhD, RN
Administrator, Health Resource Service Administration
5600 Fishers Lane
Rockville, MD  20857

Dear Dr. Wakefield,

As transplant physicians, surgeons and leaders of transplant centers and organ procurement organizations, we recognize that there is a critical shortage of donor livers in the United States. Currently, there are over 12,000 patients listed for liver transplant and typically 6000 liver transplants performed annually. We also recognize that there is a wide disparity in access to liver transplantation. This results from a variety of factors, some inherent to transplantation and some beyond (TR Srinivas, Kidney Transplant Access in the Southeastern United States: the Need for a Top-Down Transformation, AJT, 2014; 14: 1506-1511). Among the variables resulting in the disparity are differences in patient access to health care, access to insurance, race and socioeconomic background. Once a patient is listed for transplantation, despite these obstacles, large and significant differences in the rates of organ donation exist across the country (geography), as do differences in listing criteria for transplantation and center transplantation rates.

In an attempt to address this complex problem, the United Network of Organ Sharing (UNOS), a contractee to the Federal Government through the Health Resource Service Administration (HRSA) overseeing the administration of the Organ Procurement and Transplantation Network (OPTN) by listing and allocating donor organs for US transplant recipients, has put forth a “concept” proposal aimed at significantly broadening the geographic boundaries for sharing of donor livers. If this proposal becomes implemented without adequate and constructive improvements it would represent the most drastic change in liver allocation ever and would significantly disadvantage many areas of the country currently able to serve their patient populations.
We are very aware that the context promoting change dates back to the 1990’s when there was a vigorous debate within the liver transplant community surrounding disparity in liver allocation. This culminated with federal regulators imposing the "final rule" which states that:

§121.8 Allocation of organs.

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

In response to the "final rule," UNOS implemented a number of changes in liver allocation beginning in 2002 to reduce these disparities with prioritization of liver recipients based on the Model for Endstage Liver Disease (MELD) score, an objective predictor of waiting list mortality.

However, “geographic disparity” in organ access was not specified in the rule and did not become a focus of study until much later; this has historically been one of the most contentious issues in liver allocation. While broader organ sharing may help to equalize access to donor organs, these changes dramatically alter local organ availability for desperately ill patients and adversely impact many transplant centers’ abilities to care for their patients by liver transplantation, not to mention the associated costs. This proposal signals a change in local accountability, transplant center and local OPO
collaboration, and de-emphasizes local OPO outcomes: three components that are so essential to a well-functioning system.

Furthermore, we recognize that the changes sought are predicated on the basis that certain parts of the country will benefit only at the expense of other parts of the country. Wider geographic organ sharing will increase access for larger, urban transplant centers on the east and west coast while limiting organ availability to other programs, including the more rural areas of the US. A careful review of the Federal Regulations (listed above) shows that distribution of organs over as broad a geographic area as feasible is just one of several competing priorities under which the OPTN is instructed to operate. The other priorities include maintaining sound medical judgment, wise stewardship of the donated organs, and limiting wasteful and futile practices. It is the responsibility of the OPTN to find a balance between these priorities and values for the greatest good of the patients in need of solid organ transplantation.

It is important to recall that the first experiment in broader regional sharing which began in 2009 was a limited study in UNOS Region 8 (Iowa, Missouri, Kansas, Nebraska, Colorado, Wyoming) that shared organs across the region for all patients with MELD scores of 29 or greater. That system largely failed to achieve its goals of decreasing wait list mortality. After 2 years, the data revealed no differences in deaths on the waiting list; reduction in deaths from the upper MELD categories was balanced by increased deaths in the lower MELD categories (data presented at regional meeting). Shortly after MELD 29 share was voted out of region 8, a national MELD 35 share program was implemented in June 2013. While an almost immediate change in liver allocation occurred for some donor organs across long distances, the impact of this change has not been assessed. At this time sufficient data are not available to evaluate the effect of this share MELD 35 policy on either the post-transplant outcomes of these much sicker patients’ or the potential for a significant increase in cost associated with the long distant retrievals engendered. In spite of this, proposals to allow for even much broader organ sharing by decreasing the number of UNOS regions (i.e. the geographic area over which organs are distributed) from 11 to either 4 or 8 districts (“redistricting”) have been proposed by the UNOS Liver and Intestine Committee based on sophisticated modeling (albeit mathematical and not related to real time clinical data) to predict the impact of this change on liver allocation and the death rate for patients listed for transplant.
The first notification of this proposal was only made public in July, 2014, approximately two months prior to a UNOS meeting scheduled in Chicago in September 2014 where this proposal will be discussed. Thereafter, it is our understanding that the proposal will be reviewed by the UNOS Board of Directors within 60 days. However, a number of transplant programs across the nation have serious reservations about these actions, their timing, and potential consequences, intentional and unintentional. These concerns include:

1. The UNOS proposal for wider regional sharing is based on modeling data that has not been reviewed by the transplant community, nor has it been piloted clinically. Many experienced transplant clinicians and OPO executives have serious concerns about the validity of this model, including the use of outdated data that may not be reflective of current practices and inaccurate estimates of the financial and staffing resources required to implement this plan.

2. Negative effects of a proposed policy change on outcomes need to be fully considered, e.g. on posttransplant morbidity and mortality and not only removal from waitlist due to illness.

3. Reallocating livers to larger metropolitan transplant centers on the East and West Coasts has the unintended consequence of shifting resources away from transplant centers that serve large areas of the US, many of which serve rural, relatively poorer populations, thereby decreasing access for communities with high donation rates and potentially affecting the viability of smaller programs in geographically remote areas.

4. Neither Share 35 nor the proposed redistricting accounts for the one change that could solve the donor shortage: improved organ donation rates overall and in urban areas in particular. We believe any new allocation system should preserve and enhance local accountability for DSA performance (e.g. donations per unit of eligible deaths). If OPO outcomes could be improved in areas where the greatest needs exist, it is questionable if the current UNOS redistricting proposal would have been pursued.

5. Sharing for higher MELD scores should confer a survival benefit. Sharing should, in general and with few exceptions, be limited to patients with laboratory value-based MELD scores. Furthermore, sharing (and associated costs etc.) should require some minimum differential in MELD score. The current policy has seen organs travel for MELD score differences of 1. There is no evidence of a survival benefit for reallocating organs for MELD score differentials this low. More proximate local recipients should be favored if their MELD score is similar (e.g. differential of at least 3, 4, or 5) to a more geographically remote recipient.
6. Importantly, little consideration has been given to the substantially increased costs and required travel (which is inherently dangerous) for medical personnel that will be seen with increasing recovery distances and private travel. Organ acquisition charges by the OPO to the transplant centers will likely double based upon the experience of one OPO (unpublished data). No data has been presented on this critical issue to date. While it has been stated that the proposed redistricting will result in decreased costs or savings to the “system” by transplanting sicker patients, these “system savings” actually amount to realized costs (e.g. increased charter air travel, longer times in donor hospitals, need for larger surgical teams, longer length of stay and more admissions for waitlisted patients who must get sicker to get a MELD score high enough to trigger a liver to be allocated to them) that will accrue to the individual transplant centers.

7. Finally, a new allocation policy should produce a meaningful improvement in outcomes, including waitlist mortality, posttransplant mortality and graft loss and cost. We propose that a priori requirements be set for projected and actual improvements (e.g. \( \geq 5\% \) change in a key outcome and benchmarked against standard economic metrics, such as cost per QALY). Cost is a key determinant of access to healthcare, including liver transplantation. It is important that total costs are considered, including cost to patients, institutions and OPOs. Given limited fiscal resources in health care, cost is an important factor that cannot be ignored.

Therefore, the undersigned transplant centers and organ procurement organizations request

1. UNOS/OPTN members be given adequate time for presenting their concerns to the liver transplant community at the UNOS open forum in Chicago.

2. No redistricting should be discussed until the effects (patient outcomes before and after transplant and the cost for these changes) of the recently implemented Share 35 have been thoroughly evaluated. We must understand the impact of this change in allocation before undertaking an even more radical change to the system.

3. More emphasis should be given to OPO outcomes and efforts should be directed to support efforts by the OPO’s and transplant centers to raise the organ donor consent rate in geographical areas where disparities in wait times are the greatest.

4. SRTR release data that will allow individual transplant centers and OPO’s to determine the effect that the modeling scenario(s) will have on their volumes, costs, overall operations, and potential future sustainability, particularly in the rural areas of the US.
Sincerely yours,

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