UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE EXECUTIVE VICE PRESIDENT
UC HEALTH

OFFICE OF THE PRESIDENT
1111 Broadway, Suite 1400
Oakland, California 94607-5200
(510) 987-9071 Fax (510) 835-2346

October 31, 2018

Brian Shepard
Chief Executive Officer
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

Dear Mr. Shepard:

The University of California Health system, referred to as "UC Health," appreciates this opportunity to comment on the Organ Procurement and Transplant Network's (OPTN) Liver and Intestinal Organ Transplantation Committee's ("Committee") proposals to address current geographic and socio-economic disparities in the current methodology for allocating donated livers. UC Health is comprised of five nationally ranked academic medical centers located in Davis, Irvine, Los Angeles, San Diego, and San Francisco. Three of our medical centers- UCLA Health, UC San Diego Health, and UCSF Health- are among the 13 liver transplant centers in California. These three medical centers perform a great share of California's liver transplants. As safety net providers, UC Health's medical centers treat a disproportionate share of vulnerable patients. Many of our liver transplant candidates are disadvantaged by current liver allocation policy, as the prioritization given to Donation Services Areas (DSAs) and arbitrarily drawn UNOS regions results in these candidates not timely receiving liver transplants. Also, many of our candidates for liver transplants cannot afford to travel to other DSAs for their transplants. We commend the work the Committee has done to promote more equitable liver transplantation. Much of this work has been informed by the expertise of UCSF Health's Dr. Ryutaro Hirose, a former Chair of the Committee. **UC Health supports a clinically appropriate, equitable liver allocation policy that will ensure the "sickest patients get their liver transplants the quickest." We believe the Committee's proposed Acuity Circle (AC) model will result in a more clinically appropriate and fair distribution of donated livers. UC Health urges the Committee to recommend implementation of the AC model.**

Current means of allocating livers for transplantation fall far short of meeting the National Organ Transplant Act's (NOTA) final rule mandate to ensure that the allocation of organs for transplantation "shall not be based on the candidates' place of residence or place of listing."[i] Today, too many sick Californians must wait for prolonged periods of time to receive a donated liver. **The current allocation methodology's insistence on sharing livers within the current 58 local DSAs perpetuates disparities experienced across the country in liver transplantation.**

UC Health's Interest in Equitable Liver Distribution

Each of UC Health's public academic medical centers shares a public mission to provide high level patient care to every patient regardless of their ability to pay and their circumstances. We believe that every American should be able to access to affordable, safe, high-quality, medically necessary health care. Liver transplant candidates should be able to timely access a liver transplant. When Californians — or any other Americans —cannot receive a life-saving liver transplant simply due to their current place of residence, equitable access to healthcare is denied, and healthcare disparities result.

Disparity in Access to Liver Transplants

Three UC Health medical centers are liver transplant centers, and they rank among the country's highest recognized liver transplant centers. In 2017, UC Health's transplant facilities transplanted 372 livers.[1] Of those transplants, 342 came from deceased donors and were received by 322 adults and 20 children. The remaining 30 liver transplants came from living donors and were received by 29 adults and 1 child. UC Health strongly believes in federal allocation policies that will facilitate more Californians receiving timely liver transplants. Californians remain at a significant disadvantage trying to get liver transplants. The likelihood that a liver transplant recipient will die within a defined period of time if he or she does not receive a liver transplant can be measured using a risk assessment metric known as the Model for End-Stage Liver Disease (MELD) score. The higher the MELD score, the greater a patient's risk of death. The median MELD score for Californians awaiting a liver transplant is 33. Among Southern Californians, the median MELD score is outrageously high at 38, exceeding what is considered a high MELD score. Nationally, the average MELD score is 24. For liver transplant candidates with MELD scores between 21 and 34, there is a great variance in the probability that these candidates will get a liver transplant within 90 days on the basis of the regions in which the candidates reside. The state of California transplants 27 liver patients per 100 patient years of waitlist time. Compare this to the national average of 42 patients per 100 patient years of waitlist time. For candidates from different regions, studies have found a three-fold variation in death rates of waiting list candidates, a 20-fold variation in transplant rates and 10-point differences in MELD score at the time of transplant.[ii] **When compared with other liver transplant candidates across the country, Californians wait longer and only receive liver transplants when they are much sicker. The prolonged period of time Californian liver transplant candidates await receipt of a liver results in too many Californians dying before they can receive a liver transplant.**

Californians Face Demographic Barriers to Liver Transplantation

The challenges facing Californians in need of liver transplants can be explained in part by demographics in addition to geography. California suffers one of the highest rates of liver disease in the United States: 12 per 100,000 Californians have liver disease as compared to a national average of seven per 100,000.[iii] At the same time, California has one of the lowest death rates in the United States: 6.2/1,000, versus a national average of 8.2/1,000. California's lower

[1] In 2017, UCLA Health had 149 liver transplants; UC San Diego Health had 35 liver transplants; and UCSF Health had 188 liver transplants.

death rate reduces the potential supply of transplanted livers. Rather than having a pool of potential donors that matches the national rate of 71 potential donors per 1 million population, California's donor pool is only 31 potential donors per million. Moreover, donor authorization rates vary nationally by race and ethnicity. Lower rates of donor authorization typically occur among African-Americans, Hispanics and Asians, thereby exacerbating organ donation shortages in a state as diverse as California.[iv]

Studies show that Organ Procurement Organizations' (OPO) performance has little to do with Californians' access to liver transplantation. A national study demonstrated that, even if every OPO had a 100 percent liver donor authorization rate, significant geographic imbalances in supply and demand would remain, due largely to the demographic and epidemiological factors referenced above. The study's analysis found "no evidence to support the assertion that the liver allocation system transfers livers from better performing OPOs to poorer performing OPOs," and concluded that disparities in access were, instead, "strongly related to differences in demand" for liver transplantation.[v]

In fact, California's OPOs are consistently ranked among the top performing OPOs in the nation. In 2015, three of the four OPOs operated with higher-than-expected donation rates, compared to national mean donation rates, and the fourth performed essentially at the national mean.[vi] Ironically, many of the OPOs in regions that experience the easiest access to liver transplantation perform more poorly than their California counterparts. California's hospitals are committed to improving organ donations. However, increasing organ donations will always be insufficient if the distribution model remains so flawed.

Current Allocation Policy Benefits the Affluent

The current liver allocation methodology exacerbates inequity in health care access. For example, patients requiring liver transplants may register themselves at two or more transplant centers. Registration at multiple transplant centers can reduce transplant wait time by increasing the patients' chances of receiving a liver from a transplant center that has a shorter wait list and higher transplant rate. While this practice can reduce liver transplant candidates' wait times by several months, it requires candidates to travel to appointments at multiple centers and to make themselves available immediately for transplant if an organ becomes available. This requires financial resources that many potential recipients simply do not have. **Many California patients are unable to afford flying to multiple transplant centers and make themselves immediately available for a transplant, should a liver become available.**

Consequently, the most affluent liver transplant candidates are 70 percent more likely to travel to a non-local DSA than candidates in the lowest quartile.[vii] Of all adult liver transplant candidates, only 2.3 percent listed themselves in more than one region between January 1, 2005, and December 31, 2011; these candidates were disproportionately male, white, non-diabetic, college educated and privately insured. [viii] Further, recipients listed at multiple transplant centers who received a transplant outside of their area had significantly higher median incomes compared to patients who died on the waitlist —$84,946 versus $55,250. [ix] A recent study reviewed the rate of multiple listing by candidates waiting heart, lung, liver and kidney transplants and noted,

among other things, that 6 percent of the 103,332 individuals awaiting a liver transplant were on more than one DSA list — a cohort of patients who were found to be wealthier and better insured than the singly listed candidates.[x] Thus, not only does the current methodology disadvantage potential recipients based on the accident of their geography, it demonstrates the impact of wealth on the ability to obtain necessary medical interventions.

California Hospitals Support the Acuity Circle Model for Liver Allocation

UC Health believes the AC model will assist the most California liver transplant candidates. If implemented, the AC model would permit the greatest number of Californians, as well as liver transplant candidates across the country, generally, by granting the sickest patients timely access to a broader geographic area of donor hospitals. Far more than any other proposed model, the AC model meets the NOTA final rule's requirements of being based on sound medical judgment, being the best and most efficient use of organs as a national resource, and preventing a candidate's place of residency from dictating his or her access to liver transplantation.

The most common critique of the AC model is that travel time for organs will increase. However, to appropriately remedy the inequity inherent to OPTN's existing methodology for liver transplantation, candidates in some parts of the country will experience increased travel time for organs. Under the current methodology, Californians must wait longer than liver transplant candidates in other states. A benefit of the AC model is that California patients will not have to wait so many more weeks than patients in other states, mostly falling within regions characterized by a greater supply of organs for transplantation and fewer patients with high MELD scores, to receive liver transplantation. Additionally, there are benefits in the long-run for addressing the current inequity by providing more movement of donated organs. **While more travel will add to the initial costs of organ distribution, there will be considerable savings realized by reducing the cost of caring for patients with very high MELD scores. Savings could be realized by reducing the number of days a patient waiting for liver transplant has to remain hospitalized in an intensive care unit (ICU). ICU care greatly exceeds the cost of transporting organs.** Lastly, a transplant center's pecuniary gain or loss should not be a factor for consideration when evaluating the most medically appropriate and equitable organ distribution policy for patients.

The AC model will ensure the sickest patients have the broadest area from which to timely receive a liver transplant. Our liver transplant surgeons think the AC model will promote more equitable organ distribution not just for Californians who are currently grossly disadvantaged by a methodology that focuses on a candidate's place of residence using DSAs and arbitrarily drawn regions over his/her medical need, but for candidates across the country with high MELD scores needing a timely liver transplant who currently experience way higher than average wait times for transplantation as a result of the OPTN region in which they live. **The Committee's research and data evidence that the greatest number of lives will be saved implementing the AC model.[xi]**

UC Health Supports a Lower MELD Threshold for Broader 2-Circle Model

UC Health expresses great concern that the Broader 2-Circle (B2C) model recommended by the Committee does not meet the standards promoted by NOTA, the final rule implementing NOTA, or the Health Resources and Services Administration's (HRSA) July 31 letter.[xii] The MELD score bands in the B2C model are not narrow enough to ensure that current allocation disparities are addressed. UC Health thinks that to effectively reduce mortality rates, the MELD sharing threshold should be set at 25. We believe that the proposed B2C model MELD sharing threshold of 32 is way too high. Putting into effect a MELD sharing threshold of 32 would not remedy existing inequities. In fact, implementing the B2C model with a MELD sharing threshold of 32 would mean Californians must continue to get a lot sicker than persons in other parts of the country just to access a liver transplant. If the B2C model were to be implemented, our liver surgeons think the MELD sharing threshold would need to be at least 29 to address current inequities in liver allocation.

Conclusion

UC Health supports HRSA's direction to the OPTN to devise a liver allocation policy that will be equitable and prioritize patients' medical needs. We believe that of the two models proposed by the Committee, the AC model ensures the sickest patients will receive timely liver transplants. We urge the Committee to recommend to HRSA putting into effect the AC model. Failing to implement the AC model will result in too many Americans, including many Californians, continuing to not receive the timely liver transplants they need. Please refer any questions about our response to the Committee's proposal to Julie A. Clements, JD, MPP, Director of Health and Clinical Affairs, within the University of California system's Office of Federal Governmental Relations at (202)-974-6309/Julie.Clements@ucdc.edu.

Sincerely,

John D. Stobo, MD
Executive Vice President

---

[i] *See* 42 CFR 121.8(a)(8).
[ii] Yeh H, Smoot E, Schoenfeld DA, Markmann JF. Geographic Inequity in Access to Livers for Transplantation. Transplantation. 2011;91(4):479-486.
[iii] CDC (Mone citation).

[iv] UNOS OPTN OPO Quarterly Auth Rate Report 2013-05/2016 (Mone citation).
[v] Gentry et al. Liver sharing and organ procurement organization performance. Liver Transplantation 21(3) 2015.
[vi] Scientific Registry of Transplant Resources, Observed vs. Expected Donation Rates for 2015 (Mone).
[vii] Dzebisashvili et al. Following the Organ Supply: Assessing the Benefit of Inter-DSA Travel in Liver Transplantation. *Transplantation*, 95(2), 361-371. January 2013.
[viii]Parsia A. Vagefi, MD, FACS correspondence email, Sandy Feng, MD, PhD, Jennifer L. Dodge, MPH, James F. Markmann, MD, PhD, FACS, John P. Roberts, Multiple Listings as a Reflection of Geographic Disparity in Liver Transplantation. Journal of the American College of Surgeons. September 2014, Volume 219, Issue 3, Pages 496–504.
[ix] Schwartz A, Schiano T, Kim-Schluger L, Florman S. Geographic disparity: the dilemma of lower socioeconomic status, multiple listing, and death on the liver transplant waiting list. Clinical Transplantation Volume 28, Issue 10, pages 1075–1079, October 2014.
[x] Cha, A. E., "Inequality in U.S. organ transplants: Researchers detail how the wealthy game the system," Washington Post, November 12, 2015.

[xi] *See* Table 4 at https://optn.transplant.hrsa.gov/media/2687/20181008_liver_publiccomment.pdf
[xii] *See* https://optn.transplant.hrsa.gov/media/2583/hrsa_to_optn_organ_allocation_20180731.pdf