The Honorable Alex M. Azar, II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Azar,

We write today to urge that you immediately rescind the directive of Health Resources and Services Administration (HRSA) Administrator George Sigounas to the Organ Procurement and Transplantation Network (OPTN) dated July 31, 2018. The directive requires OPTN to implement a new policy for the allocation and distribution of livers from deceased donors and halt implementation of the liver distribution and allocation policy that was approved by the OPTN/United Network for Organ Sharing (UNOS) Board of Directors in December 2017 (the December 2017 Policy). Administrator Sigounas’s directive is a clear departure from the evidence-based and consensus-driven process that led to the December 2017 Policy, and we urge you to reverse course on this misguided and hasty policy change.

The December 2017 Policy was approved by the OPTN/UNOS Board of Directors after years of debate and consensus-building. It was based on substantial deliberations among experts in the liver transplant community, two separate public notice-and-comment processes, two day-long public forums, and intensive review of multiple data sets analyzing the impact the proposal would have on various components of transplantation. The December 2017 Policy was designed to address longstanding concerns about the geographic equity of donated livers by providing increased access for the sickest patients over a broader geographic area. This framework was the product of extensive expert-driven debate that was envisioned when Congress established the OPTN to set organ transplant policy in the United States.

On May 30, 2018, a letter was submitted to HHS from a New York law firm that asked the Department to direct OPTN to abandon the December 2017 Policy. This letter was deemed a “critical comment” by HHS. On July 13, 2018, a lawsuit was filed in the U.S. Southern District of New York on behalf of plaintiffs in New York, Massachusetts and California, alleging that the use of Donation Service Areas (DSAs) and OPTN Regions in the allocation methodology for donated livers is illegal. In response to the lawsuit and the letter, HRSA directed OPTN on July 31, 2018 to remove DSAs and OPTN regions from its allocation methodology prior to the OPTN Board Meeting in December 2018.
We are extremely concerned by this new course of action taken by HRSA and OPTN, as the December 2017 Policy is in compliance with the law. Administrative agencies should not respond to pending litigation by ordering destabilizing and potentially reckless changes in policy. We are also dismayed at the accelerated process through which this change is being pursued, limiting opportunity for dissent or thoughtful consideration of the potential direct and indirect consequences. These concerns are shared by the Attorney Generals from four states who demanded that the directive be rescinded in a letter to you on August 21, 2018.

The abandonment of the December 2017 policy will have far reaching effects that will create significant patient access concerns within our districts and states. For example, initial stakeholder analysis of the proposals under consideration by the OPTN Liver and Intestine Committee predict changes in the number of liver transplants in some states may decrease by as much as 50%. These significant variances in overall transplant volume will endanger patient access to liver transplant services in areas of the country that already have limited access to liver transplant programs.

Removing DSAs and OPTN Regions from the liver allocation and distribution policy will not solve the core issue confronting the transplant community today – a shortage of donated organs. There has been significant progress made to improve and sustain the successful performance of organ donation efforts in the Midwest, Southeast, and Northwest. The Department, through the Centers for Medicare & Medicaid Services oversight of organ procurement organizations (OPO), should be pursuing policies that promote better OPO performance in all parts of the country – not policies that harvest organs from high-performing regions to the benefit of low-performing areas. The redistribution of livers brought about by removing DSAs and OPTN Regions from the liver distribution and allocation policy will disincentivize organ donation, reduce organ availability in rural and minority communities, and destabilize local transplant centers. These are unacceptable outcomes.

We strongly urge that you immediately rescind the directives outlined in the July 31 letter from Administrator Sigounas, halt any activities to alter or eliminate the December 2017 Policy, and allow the December 2017 Policy to be fully implemented on schedule. We look forward to your prompt reply to this urgent matter.

Sincerely,

Kevin Yoder
Member of Congress

Eddie Bernice Johnson
Member of Congress
Louie Gohmert  
Member of Congress

Lynn Jenkins  
Member of Congress

Ron Estes  
Member of Congress