



SEP 29 2014

The Honorable Kevin Yoder
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Yoder:

Thank you for your letter regarding the Organ Procurement and Transplantation Network (OPTN) liver allocation policy, and specifically, the liver allocation concept document released by the OPTN on June 16, 2014.

The Health Resources and Services Administration (HRSA) is responsible for overseeing the operation of the OPTN to ensure equitable allocation of donor organs for transplantation. OPTN organ allocation policies are developed through a deliberative process with input from experts in the field, transplant recipients, candidates, donor family members, living donors, and from public comment.

Through the OPTN's policy development process, the OPTN Liver and Intestinal Organ Transplantation Committee is working with the Scientific Registry of Transplant Recipients, operated under contract by HRSA, to examine potential new districts for liver allocation that are based on empirical data and mathematical methods. In your letter, you express concern regarding potential adverse impacts of proposed changes on individuals with liver disease. The OPTN has explained that the goal of any proposed revision to the OPTN regional structure for purposes of liver allocation will be to increase access to livers for patients with the greatest medical urgency and to decrease geographic disparity for such patients.

The liver allocation concept document does not represent a final policy proposal. On September 16, 2014, the OPTN Liver and Intestinal Organ Transplantation Committee held a public forum to discuss the concept document. During the forum, stakeholders had an opportunity to provide feedback and express concerns, including the impact on organ travel times and potential disproportionate impact by geographic region. These concerns will be taken into consideration as the OPTN develops a formal policy proposal. Once a policy proposal has been finalized, there will be an additional opportunity for broad public comment as part of the established OPTN policy development process.

Any change in the OPTN liver allocation policy must be consistent with the principles established in the National Organ Transplant Act of 1984, as amended, and the regulations governing the operation of the OPTN, which articulate the goals to be achieved through OPTN organ allocation policies. The regulations require allocation policies be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements), per 42 CFR § 121.8. HRSA will continue to monitor developments regarding proposed changes to the OPTN liver allocation policy for compliance with the requirements set forth in the OPTN final rule for organ allocation policies and the OPTN policy development process.

Your letter also addressed the OPTN liver allocation policy implemented last year, known as the "Share 35 Regional" policy. The goal of the Share 35 Regional policy is to minimize deaths for patients with liver disease on the waiting list. HRSA and the OPTN will also continue to monitor and analyze the effects of the "Share 35" liver allocation policy implemented last June as any changes in liver distribution policy are considered. Initial results indicate that the policy goals of "Share 35" are being met, and implementation is proceeding as expected.

As mentioned in your letter, a 2010 Appropriations Conference Report (Report 111-366) required that the OPTN submit, 6 months prior to implementation of changes to the OPTN liver allocation policy, a report on the potential impact of any changes to broaden the geographic allocation of livers. The OPTN submitted the report to the House and Senate Appropriations Committees in November 2011 in advance of implementation of the "Share 35" liver allocation policy, which was approved by the OPTN Board of Directors in June 2012 and officially implemented in June 2013. Soon after the report was submitted and again last spring, Appropriations Committee staff indicated to the OPTN that the report satisfied the conference report requirement.

Thank you again for your interest in the national liver allocation policy. A copy of this letter has been sent to the co-signers of your letter.

Sincerely,

A handwritten signature in cursive script that reads "Mary K. Wakefield". The signature is written in black ink and is positioned above the printed name and title.

Mary K. Wakefield, Ph.D. R.N.
Administrator