

## HHS Properly Handled New Liver Transplant Rule: 11th Circ.

Law360 (September 26, 2019, 7:56 PM EDT) — The Eleventh Circuit found that the U.S. Department of Health and Human Services was not required to refer a new nationwide liver transplant allocation policy to an advisory committee nor was it mandated to go through the public notice-and-comment process to implement the regulation.

A three-judge panel of the appeals court on Wednesday upheld a Georgia federal judge's denial of a preliminary injunction in a suit filed by four liver transplant candidates and hospitals to block HHS' changes to the previous liver transplant policy.

The suit alleges, among other things, that the changes to the rule that determines which patients — among the more than 12,000 currently on the national waiting list — will not prioritize people with the most urgent medical need within donors' geographic region. The policy was set to be implemented in April, but has been put on hold while the dispute plays out in court.

The panel was not convinced with the plaintiffs' assertions that HHS violated the Administrative Procedure Act during the development of the new policy and that the agency's Advisory Committee on Organ Transplantation has a broader role in policy development than the department's secretary.

"As particularly relevant here, consistent with HHS' treatment of prior organ allocation policies, the secretary didn't refer the new policy to the Advisory Committee on Organ Transplantation or publish it in the Federal Register for public comment," U.S. Circuit Judge Kevin Newsom wrote.

Furthermore, HHS' policy, in this case, makes it clear the "secretary's discretion remains largely intact — the secretary is only required to consult the advisory committee in a few circumstances," the order said.

But the panel has remanded the case because U.S. District Judge Amy Totenberg failed to examine two other claims in the suit: that HHS and United Network for Organ Sharing — a nonprofit that devised the new rule and is overseeing organ distribution in the U.S. on the agency's behalf — acted arbitrarily and capriciously in adopting the regulation and that the changes deprived plaintiffs' of their due process rights.

"We are wary of diving headfirst into claims that the district court hasn't yet considered, and we are especially wary of doing so with respect to these claims — both of which will likely turn on fact- and context-intensive questions that the district court is better equipped to decide in the first instance," the panel said.

It also said for the plaintiffs to have a "cognizable due process claim" against United Network, the private government contractor's actions in adopting the new policy must be considered "state action."

On the arbitrary and capricious claim, the panel said the district court's fact-finding should determine whether HHS' decision to direct the new policy's development to the contractor was appropriate; if the contractor had used the correct procedures when crafting the policy; if it adequately considered public comments; what role, if any, did the expedited timeline play to implement the policy; and if the regulation substantively complies with statutory and regulatory requirements.

On the due process claim, "some unavoidably fact-sensitive" questions that should be asked are: Do the plaintiffs "have a life, liberty, or property interest that has been affected by the new policy? If so, did United Network's policies adequately afford them an opportunity to be heard? Did HHS?" according to the order.

Under the current policy, donated livers are offered to registered patients with the greatest need and closer to donors in a geographic region. But the new rule requires that the organ is distributed to the most severe patients within a 500-mile radius.

The suit challenging the new rule was filed just days before the policy's April 30 implementation date. The plaintiffs — including Emory University Hospital in Georgia, Indiana University Health and Oregon Health and Science University, which serve as transplant centers — said it would slash access to 256 fewer livers and cause some facilities to reach into other pockets of the country where the liver shortage is not so severe.

But HHS said United Network has defended the rule change, saying it would result in a more equitable distribution of livers for all candidates on the waiting list and lead to fewer deaths each year.

Counsel for the plaintiffs did not immediately respond to requests for comment Thursday.

An HHS representative referred Law360 to the U.S. Department of Justice for comment Thursday; the agency did not immediately reply. An attorney for United Network declined to comment.

U.S. Circuit Judges Charles Wilson and Kevin Newsom and U.S. District Judge Scott Coogler of the Northern District of Alabama sat on the panel for the Eleventh Circuit.

The plaintiffs are represented by Peter Canfield, Courtney A. Carrell, Glenn Lorin Krinsky and John M. Majoras of Jones Day, William Roquemore Taylor of Blank Rome LLP, and **Jason Scott Alloy of Robbins Ross Alloy Belinfante & Littlefield LLC**.

HHS is represented by Bradley Hinshelwood of the U.S. Department of Justice's Civil Division, Appellate Staff, Michael Drezner of the DOJ's Civil Division and Martin Totaro of the U.S. Securities & Exchange Commission's Office of the General Counsel.

United Network is represented by Jay S. Blumenkopf, Sara Anderson Frey and Steven James Flynn of Gordon Rees Scully Mansukhani LLP, and Linda T. Coberly, Lauren Gailey, Melanie Laiyee Lee, Daniel D. Rubinstein, Sean H. Suber and Thomas G. Weber of Winston & Strawn LLP.

The case is Callahan et al. v. U.S. Department of Health and Human Services et al., case number 19-11876, in the U.S. Court of Appeals for the Eleventh Circuit. The district court case is Callahan et al. v. U.S. Department of Health and Human Services et al., case number 1:19-cv-01783, in the U.S. District Court for the Northern District of Georgia.