

Findings and Recommendations for the HIV Organ Policy Equity (HOPE) Act

Session Law 2017-103, Section 2



Report to

**Joint Legislative Oversight Committee on Health and
Human Services**

by

N.C. Department of Health and Human Services

January 1, 2018

REPORTING REQUIREMENTS

Session Law 2017-103, Section 2 provides:

The Department of Health and Human Services shall examine P.L. 113- 51, HIV Organ Policy Equity (HOPE) Act, and the Final Safeguards and Research Criteria publication by the U.S. Department of Health and Human Services and National Institutes of Health to determine public health safeguards, regulations, and statutory changes necessary for consideration by the General Assembly. The Department shall submit a report of findings and recommendations, including any necessary statutory changes, to the Joint Legislative Oversight Committee on Health and Human Services on or before January 1, 2018.

BACKGROUND

There is a national shortage of kidney and liver donations which has resulted in long wait times for available organs. The national HIV Organ Policy Equity (HOPE) Act was enacted on November 21, 2013, and acknowledges international scientific literature that has shown transplantation of HIV positive organs into HIV positive recipients can be done successfully and could be of great benefit. The HOPE Act called for the Secretary of the U.S. Department of Health and Human Services (HHS Secretary) to develop and publish criteria for research relating to transplantation of organs from HIV positive donors into HIV positive recipients. The final research criteria were published on November 23, 2015 and referenced in The Organ Procurement and Transplantation Network (OPTN) Final Rule (42 CFR 121.6).

The HOPE Act requires that all transplantations of HIV positive organs into HIV positive recipients must occur under an institutional review board (IRB) approved research protocol that is compliant with federal regulations governing human subjects' research. The Final Safeguards and Research Criteria are meant to support the acquisition of new clinical knowledge and mechanistic insights about HIV positive to HIV positive organ transplantation in the United States. The results of this research will be evaluated by the HHS Secretary and the OPTN to determine whether and how the OPTN standards for organ transplantation shall be revised to address HIV positive organ donors in the future.

FINDINGS, RECOMMENDATIONS AND CURRENT ACTIVITIES

After review of the published research criteria, NC DHHS' Division of Public Health (DPH) has determined the federal public health safeguards and regulations outlined in the document published by the federal HHS Secretary are adequate to ensure the continued safety of North Carolinians.

DPH has determined that no statutory changes are necessary for consideration by the General Assembly. However, the current wording of 10A NCAC 41A .0202 (Control Measures – HIV) creates a conflict with the Hope Act. Specifically, section 1(c) of this administrative code prohibits HIV infected individuals from donating or selling organs, without exception.

DPH has identified the necessary changes to 10A NCAC 41A .0202 (Control Measures – HIV) to resolve this conflict. The revised rule incorporates the HOPE Act by reference which will allow

for the transplantation of HIV positive organs into HIV seropositive individuals, when done as part of a research study compliant with the mandates of the HOPE Act. The proposed changes have been going through the standard rule making process, with an anticipated effective date of January 1, 2018.