

Mini-Brief

Change to HOPE Act Variance Expiration Date

OPTN/UNOS Organ Procurement Organization Committee

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Contents

Executive Summary	2
What problem will this proposal address?	3
Why should you support this proposal?	3
How does this proposal impact the OPTN Strategic Plan?	3
How will the OPTN implement this proposal?	4
How will members implement this proposal?	4
Will this proposal require members to submit additional data?	4
How will members be evaluated for compliance with this proposal?	4
Policy Language	5

Change to HOPE Act Variance Expiration Date

Affected Policies: Policy 15.7 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors)
Sponsoring Committee: Organ Procurement Organization Committee
Board of Director's Date: December 4-5, 2017

Executive Summary

The HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, allows research to be conducted on the transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The legislation required the OPTN to revise its policies “not later than 2 years after the enactment” to allow this research to begin. This statutory requirement was met with policies being approved in June 2015 and programming implemented in November 2015.

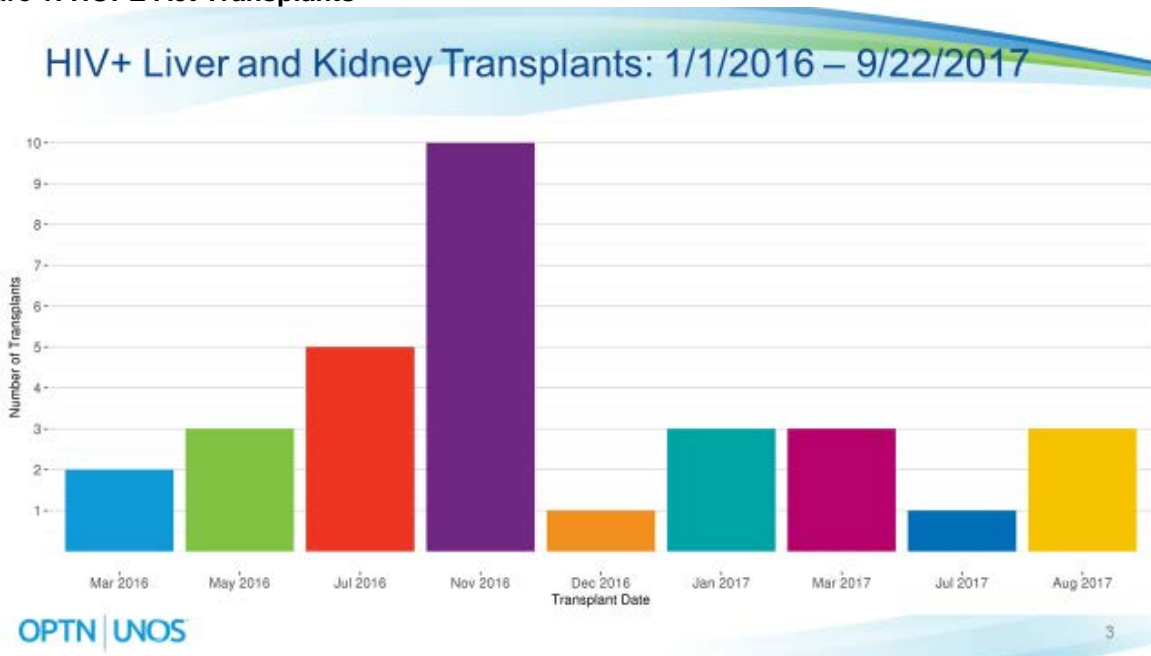
The HOPE Act also states that “not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality.” The number of transplants performed since implementation has remained low and the ability to evaluate the results of research has not been determined. Therefore, the OPO Committee is recommending the upcoming January 1, 2018 expiration date for the variance be extended to January 1, 2020.

What problem will this proposal address?

The HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, allows research to be conducted on the transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The HOPE Act states that “not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality. When the Board originally approved the HOPE Act variance in June 2015 there was not a defined expiration date so the Executive Committee subsequently adopted an expiration date of January 1, 2018.

The number of transplants performed as part of the research remains low. Figure 1 shows the number of transplants performed each month since the first transplant was performed in March 2016. **Note:** There have been 3 additional transplants performed in October.

Figure 1: HOPE Act Transplants



Why should you support this proposal?

The goal of HOPE Act research is to study the feasibility and safety of performing transplants from HIV positive donors into HIV positive candidates. While the number of transplants has remained low, there is little debate about the importance of this research. While the plan to “evaluate the results of the research” has not been determined, the OPO Committee agreed that the variance should be extended. The current expiration date is set for January 1, 2018. During its October 25, 2017 meeting, the OPO Committee unanimously voted to extend the expiration date to January 1, 2020.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: This specific proposal does not impact this strategic goal but the previously approved proposal supports the goal by allowing HIV positive recipients to utilize kidneys or livers from HIV positive donors, thus increasing the pool of organs available for transplant.

Improve equity in access to transplants: There is no impact to this goal.

Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.

Promote living donor and transplant recipient safety: This specific proposal does not promote transplant recipient safety but the previously approved variance does promote recipient safety by allowing the OPTN to review IRB data safety monitoring reports to identify issues or trends across multiple research studies.

Promote the efficient management of the OPTN: This proposal promotes the efficient management of the OPTN by extending the expiration date for the HOPE Act variance.

How will the OPTN implement this proposal?

This proposal does not require implementation. The previously approved variance was implemented on November 21, 2015.

How will members implement this proposal?

This proposal does not change the previously approved variance requirement for transplant hospitals participating in a HOPE Act IRB approved research study to provide the OPTN with a schedule of deadlines for data safety monitoring reports and provide reports to the OPTN according to the schedule.

Will this proposal require members to submit additional data?

This proposal does not change the previously approved requirements for members participating in the HOPE Act variance to submit IRB data safety monitoring reports to the OPTN to allow for ongoing review of research studies to ensure patient safety. Collecting data for this purpose is consistent with the OPTN Principles of Data Collection.

How will members be evaluated for compliance with this proposal?

This proposal does not impact the previous compliance requirements for members. Before a transplant hospital can have HIV positive organs allocated to their candidates, the hospital must submit a request for an open variance that will include: 1. A detailed schedule of required deadlines for IRB data safety monitoring board reports. 2. A copy of the IRB approval letter

1 Policy Language

2 **RESOLVED**, that the expiration date for Policy 15.7 (Open Variance for the Recovery and
3 Transplantation of Organs from HIV Positive Donors), as set forth below, scheduled to expire on
4 January 1, 2018, be extended to January 1, 2020.
5

6 **15.7 Open Variance for the Recovery and Transplantation of** 7 **Organs from HIV Positive Donors**

8 This variance applies to members participating in an institutional review board (IRB) approved research
9 protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from
10 donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs
11 into HIV positive recipients, including Health and Human Services (HHS) research criteria pertaining to
12 transplantation of organs from HIV positive donors, as applicable.
13

14 Transplant hospitals participating in this variance must submit *all* of the following to the OPTN Contractor:
15

- 16 1. A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the
17 requirements in the HHS research criteria.
- 18 2. IRB data safety monitoring reports at each deadline in the schedule.
19
20

21 **15.7.A Requirements for Allocating HIV Positive Deceased Donor Organs**

22 In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive
23 organs only after determining the potential deceased donor is HIV positive and the HIV positive
24 candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must
25 only allocate HIV positive organs to HIV positive candidates appearing on the match run, except
26 in cases of directed donation. The OPO must verify that the potential recipient is registered as a
27 HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C:*
28 *Transplant Hospital Requirements for Transplantation of HIV Positive Organs.*
29

30 **15.7.B Requirements for Allocating HIV Positive Living Donor Organs**

31 In addition to the requirements of the OPTN Final Rule, the recovery hospital must confirm that
32 the potential living donor is HIV positive and the potential recipient is willing to accept an HIV
33 positive organ as part of a research protocol.
34

35 **15.7.C Transplant Hospital Requirements for Transplantation of HIV** 36 **Positive Organs**

37 In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant HIV
38 positive organs only if *all* of the following conditions are true:
39

- 40 1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is
41 participating in an institutional review board approved research protocol that meets the
42 requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from
43 HIV positive individuals.
- 44 2. The transplant hospital obtains informed consent from the potential transplant recipient to
45 participate in the institutional review board protocol that meets requirements in the OPTN Final
46 Rule.
- 47 3. The transplant hospital meets the informed consent requirements according to *Policy 15.3*
48 *Informed Consent of Transmissible Disease Risk.*
49

50 In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or
51 livers, the transplant hospital must complete a two-person reporting and verification process. This
52 process must include two different individuals who each make an independent report to the
53 OPTN Contractor that the candidate is willing to accept an HIV positive organ as part of a
54 research protocol.

55
56 Transplant hospitals must notify the OPTN Contractor if it is no longer participating in an IRB
57 approved research protocol that meets the requirements in the OPTN Final Rule regarding the
58 recovery and transplantation of organs from HIV positive individuals.

59
60 The OPTN Contractor may release to the public the names of members participating in this
61 variance.

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