

effective on May 5, 2015, as provided in the February 19, 2015 direct final rule.

Accordingly, the amendments to 40 CFR 80.1453, 80.1616 and 80.1621 on February 19, 2015 (80 FR 9078), are withdrawn as of May 5, 2015.

#### List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Diesel fuel, Fuel additives, Gasoline, Imports, Incorporation by reference, Labeling, Motor vehicle pollution, Penalties, Petroleum, Reporting and recordkeeping requirements.

Dated: April 30, 2015.

**Gina McCarthy,**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### 42 CFR Part 86

#### Grants for Education Programs in Occupational Safety and Health

##### *CFR Correction*

■ In Title 42 of the Code of Federal Regulations, Parts 1 to 399, revised as of October 1, 2014, on page 668, in § 86.33, in paragraph (b), remove the term “068”.

[FR Doc. 2015-11141 Filed 5-7-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### 42 CFR Part 121

**RIN 0906-AB05**

#### Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity Act

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the regulations implementing the National Organ Transplant Act of 1984, as amended, (NOTA) pursuant to statutory requirements of the HIV Organ Policy Equity Act (HOPE Act), enacted in 2013. In accordance with the mandates of the HOPE Act, this regulation removes the current regulatory provision that

requires the Organ Procurement Transplantation Network (OPTN) to adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus (HIV).

In its place, this regulation includes new requirements that organs from individuals infected with HIV may be transplanted only into individuals who are infected with HIV before receiving such organs and who are participating in clinical research approved by an institutional review board, as provided by regulation. The only exception to this requirement of participation in such clinical research is if the Secretary publishes a determination in the future that participation in such clinical research, as a requirement for transplants of organs from individuals infected with HIV, is no longer warranted.

In addition, this regulatory change establishes that OPTN standards must ensure that any HIV-infected transplant recipients are participating in clinical research in accordance with the research criteria to be published by the Secretary. Alternately, if and when the Secretary determines that participation in such clinical research should no longer be a requirement for transplants with organs from donors infected with HIV to individuals infected with HIV, the regulation mandates that the OPTN adopt and use standards of quality, as directed by the Secretary, consistent with the law and in a way that ensures the changes will not reduce the safety of organ transplantation.

**DATES:** This final rule is effective June 8, 2015.

#### **FOR FURTHER INFORMATION CONTACT:**

Robert W. Walsh, Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 8W37, Rockville, MD 20857; or by telephone (301) 443-7577.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration's (HRSA), Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) is responsible for overseeing the operation of the nation's Organ Procurement and Transplantation Network (OPTN), which has responsibilities including the equitable allocation of donor organs for transplantation. The allocation of organs is guided by organ allocation policies developed by the OPTN in accordance with the regulations governing the

operation of the OPTN (sometimes referred to as the “OPTN final rule” and herein referred to as “OPTN regulations”) (42 CFR part 121). The OPTN is also charged with developing policies on many subjects, including standards of quality pertaining to organs procured for use in transplantation. In addition to the efficient and effective allocation of donor organs through the OPTN, the Secretary also supports efforts to increase the supply of donor organs made available through transplantation.

##### **II. Summary of the HOPE Act**

Prior to the enactment of the HOPE Act, Public Law 113-51 (November 21, 2013), NOTA required the OPTN to adopt and use standards of quality for preventing the acquisition of organs from individuals known to be infected with HIV. This requirement was further incorporated into regulation at 42 CFR 121.6(b). Thus, OPTN members were prohibited from transplanting organs from individuals known to be infected with HIV into patients (including patients infected with HIV).

The HOPE Act made an important change with respect to the transplantation of organs from individuals infected with HIV. Pursuant to the HOPE Act, organs from individuals infected with HIV may be transplanted so long as two sets of requirements are satisfied. First, organs from individuals infected with HIV may be transplanted only into individuals who were infected with HIV prior to receiving such an organ.

Second, transplants from individuals infected with HIV are subject to one of two oversight frameworks. Specifically, under the initial framework envisioned by the HOPE Act, all recipients of organs from individuals infected with HIV must be participating in clinical research approved by an institutional review board under research criteria to be published by the Secretary as described in the HOPE Act and the standards of quality implemented by the OPTN pursuant to the HOPE Act. Based on this change, all transplant centers conducting such clinical research will be required to comply with research criteria published by the Secretary under subsection (a) of section 377E of the Public Health Service Act, as amended. Alternately, if the Secretary determines that participation in such clinical research is no longer warranted as a requirement for transplants of organs from individuals infected with HIV, the Secretary will publish such a determination. The Secretary must then, consistent with the HOPE Act, direct the OPTN to revise its standards, consistent