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Accordingly, the amendments to 40 CFR 80.1453, 80.1616 and 80.1621 on February 19, 2015 (80 FR 9078), are withdrawn as of May 5, 2015.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

[FR Doc. 2015–10487 Filed 5–6–15; 4:15 pm]

BILLING CODE 6560–50–P

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]

BILLING CODE 1505–01–D

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

with applicable law, in a way to ensure that the changes will not reduce the safety of organ transplantation. Such a direction may only occur, if at all, after the Secretary reviews the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards of quality with respect to specific issues identified in the HOPE Act.

As noted above, the HOPE Act directs the Secretary to develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving an HIV-infected organ. These research criteria will be published in a separate document and public comments will be solicited on such research criteria.

The HOPE Act also requires the OPTN to revise standards of quality for the acquisition and transportation of donated HIV-infected organs to the extent determined necessary by the Secretary to allow the conduct of research in accordance with the research criteria published by the Secretary (unless and until such time that the Secretary publishes a determination that participation in such clinical research is no longer warranted for transplants involving organs from donors infected with HIV).

Consistent with these directives, the HOPE Act directs the Secretary to revise current regulations (specifically, 42 CFR 121.6) that direct the OPTN to adopt and use standards for preventing the acquisition of organs from individuals infected with HIV, which effectively prevent the conduct of research relating to the transplantation of organs procured from individuals infected with HIV into recipients infected with HIV. The HOPE Act mandates that such regulatory revisions are to be made not later than two years after the date of enactment of the HOPE Act. That two year period will end on November 21, 2015. The Department is issuing this final rule under that statutory directive.

III. Summary of This Final Rule

The Department issues this final rule to fulfill the HOPE Act's mandate that the Secretary amend 42 CFR part 121 to permit the conduct of research involving the transplantation of organs from individuals infected with HIV into persons who are infected with HIV. This final rule removes the current regulatory prohibition against such transplants and makes clear that HIV-infected transplants may occur provided all of the HOPE Act's requirements are satisfied.

Although the HOPE Act also provides the Secretary with discretion to determine what criteria should apply to the conduct of such research, the Secretary is not promulgating such research criteria as part of this regulation. As noted above, the Secretary will publish such research criteria in a separate publication. The purpose of this regulation is to modify the regulations governing the operation of the OPTN to make such regulations consistent with the framework set forth in the HOPE Act.

Once this regulation is effective, the OPTN regulations will provide that organs from individuals infected with HIV may be transplanted only into individuals who are infected with HIV before receiving such organ(s). Thus, the OPTN final rule will not permit the transplantation of organs from individuals infected with HIV into individuals who are not infected with HIV. In addition, organs from individuals infected with HIV may only be transplanted into recipients who are participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the forthcoming research criteria to be published by the Secretary until such time that the Secretary publishes a determination that participation in such clinical research, as a requirement for transplants of organs from individuals infected with HIV, is no longer warranted. If the Secretary publishes such a determination, that transplants of organs from individuals infected with HIV can occur outside of the Secretary's research criteria, she will do so using appropriate procedures (*e.g.,* notice and comment rulemaking under the Administrative Procedure Act unless inapplicable or unless an exception applies). At that time, and as outlined in 42 CFR 121.6(b)(3), as added by this final rule, the OPTN must adopt and use standards of quality with respect to organs infected with HIV as directed by the Secretary, consistent with the applicable statutory authority (42 U.S.C. 274), and in a way that ensures the changes will not reduce the net safety of organ transplantation. The Secretary may also determine that further changes to the OPTN regulations are warranted if and when she determines that transplants of organs from individuals infected with HIV need not be conducted in accordance with the research criteria developed under the HOPE Act. The Secretary may amend the OPTN regulations and transplant centers conducting transplants with organs from donors infected with HIV into recipients with HIV will be obliged to comply with any new regulatory provisions.

IV. Explanation of Final Rule Without Notice and Comment

In accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), agencies are permitted to waive the use of notice and comment procedures in issuing regulations when such agencies, for good cause, find that notice and public comment procedures are impracticable, unnecessary, or contrary to the public interest and when agencies incorporate their findings and a brief explanation of their rationale in such regulations. The amendment to 42 CFR 121.6 made by this regulation is required by the HOPE Act. 42 U.S.C. 274f–5(b)(2). Because the changes made by this rule directly implement changes to the governing statute made by the HOPE Act, and because the Secretary is not undertaking discretionary rulemaking concerning the OPTN (but is instead directly following mandated changes in the law), the Secretary has determined, under 5 U.S.C. 553, that it is unnecessary and impracticable to follow proposed rulemaking procedures in this instance.

Thus, the Secretary is waiving the public notice and comment procedures in the interest of implementing the changes set forth in the HOPE Act, to enable persons infected with HIV to receive organs from individuals infected with HIV as long as all of the requirements set forth in the HOPE Act are satisfied and to enable the OPTN to revise its standards of quality, consistent with the HOPE Act.

V. Economic and Regulatory Impact

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations require special analysis if they are found to be ''significant'' because of their cost, adverse effects on the economy, inconsistency with other agency actions, budgetary impact, or the raising of novel legal or policy issues. In addition, the Regulatory Flexibility Act of 1980 (RFA) requires that agencies analyze regulatory proposals to determine whether they create a significant economic impact on a substantial number of small entities. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options. ''Small entity'' is defined in the RFA as ''having the same meaning as the terms 'small business,' 'small

organization,' and 'small governmental jurisdiction.' ''

The Secretary has determined that minimal resources are required to implement the requirements in this rule because the initial phase of implementation, after the Secretary develops research criteria, will be the conduct of research involving transplants of organs from HIV-infected donors into HIV-infected recipients. As such, the change in standards of quality will initially only impact Organ Procurement Organizations and transplant hospitals choosing to enroll patients in research protocols. In addition, the number of HIV-infected transplants, and the number of institutions performing HIV-infected transplants, will be small. Cost and burden estimates refer to the research phase of implementation only. Should the Secretary determine, after reviewing the results of scientific research, that the standards of quality referenced above should be modified for the entire transplant system, the Secretary will, in accordance with the HOPE Act, direct the OPTN to revise such standards, consistent with applicable law and in a way that ensures the changes will not reduce the safety of organ transplantation. At that time, the Secretary may revise the Department's impact analysis. Therefore, in accordance with the RFA and the Small Business Regulatory Flexibility Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary also has determined that this rule does not meet the criteria for an economically significant rule as defined by Executive Order 12866 and will have no major effect on the economy or Federal expenditures. The Department has determined that this rule is not a major rule within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995. This rule is not being treated as a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

The provisions of this rule will not affect the following elements of family well-being: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. As stated above, this rule modifies the regulations governing the OPTN based on legal authority.

VI. Impact of the New Rule

This rule has the effect of fulfilling the HOPE Act's statutory mandate requiring the Secretary to amend OPTN regulations to permit the conduct of research involving the transplantation of organs from individuals infected with HIV into persons who are infected with HIV. This final rule removes the current regulatory prohibition against HIV-infected transplants and makes clear that HIV-infected transplants may occur so long as all of the requirements described in the HOPE Act are satisfied. OPTN members will be required to comply with requirements set forth in the OPTN final rule, including those pertaining to data submission as set forth in 42 CFR part 121, as applied to organs recovered from HIV-infected individuals.

VII. Paperwork Reduction Act of 1995

The Department has determined that at this time, the amendment described in this rule imposes minimal additional data collection requirements beyond those already imposed by current regulations, which have been approved by the Office of Management and Budget. The current data collection requirements in the OPTN final rule approved by the OMB under the Paperwork Reduction Act of 1995 and assigned control numbers OMB No. 0915–0157 (for organ donors, candidates, and recipients) and OMB No. 0915–0184 (for OPTN membership application data) will be only slightly impacted by this rule. Current OPTN forms already include information about HIV testing and a donor's HIV status. HRSA anticipates that OPTN candidate registration forms will be updated in the future to include a question regarding the candidate's participation in research studies conducted under the authority of the Act. In addition, certain OMB-approved forms will be updated in the future to include results of HIV blood tests using Nucleic Acid Test (NAT) methodology. However, the inclusion of this information is not based upon the regulatory changes made by the HOPE Act, but is instead responsive to revised Public Health Service guidelines published in 2013. The burden for this data collection is anticipated to be small given the projected number of research participants (<1% of annual transplants at the outset). Finally, it is possible that the OPTN will conduct additional data collections to implement the changes in law created by the Act. For example, when the Secretary publishes research criteria under the Act, it is possible that such criteria will make recommendations concerning data that would be helpful for the Secretary to review in assessing research on transplants involving organs from individuals infected with HIV. In that event, the Department may choose to incorporate some of those data elements into OPTN forms and data collection. Alternately, the OPTN may determine independently that it wishes to capture additional data with respect to OPTN members participating in research under the HOPE Act. This rule reflects the Department's current assessment as to the likely data collections that will be imposed by virtue of this regulation. If, in the future, the Department or the OPTN determine that additional data should be collected in implementation of this regulation, the Department will notify the public of any proposed data collections and solicit comments consistent with the Paperwork Reduction Act.

The estimated number of respondents included in the table below is based on the current number of OPTN transplant hospital members. The number of transplant hospital members will vary as new members are approved for OPTN membership, and/or members relinquish their OPTN membership when a member ceases activity related to organ transplantation. As such, while the total burden hours may change slightly from the estimate below, the table below is an accurate representation of the current estimated annual reporting burden.

The estimated annual reporting burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours (cost)
Heart Candidate Registration	133	1	133	0.08	11 ($286)

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours (cost)
Lung Candidate Registration	68	1	68	0.08	5 ($130)
Heart/Lung Candidate Registration	67	1	67	0.08	5 ($130)
Kidney Candidate Registration	236	1	236	0.08	19 ($494)
Pancreas Candidate Registration	137	1	137	0.08	11 ($286)
Kidney/Pancreas Candidate Registration	137	1	137	0.08	11 ($286)
Pancreas Islet Candidate Registration	20	1	20	0.08	2 ($52)
Liver Candidate Registration	139	1	139	0.08	11 ($286)
Intestine Candidate Registration	41	1	41	0.08	3 ($78)
Total	978	9	978	0.72	78 ($2,028)

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Organ transplantation, Reporting and recordkeeping requirements.

Dated: April 21, 2015.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: May 1, 2015.

Sylvia M. Burwell,

Secretary.

Therefore, for the reasons stated in the preamble, the Department of Health and Human Services amends 42 CFR part 121 as follows:

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 1. The authority citation for part 121 is revised to read as follows:

Authority: Sections 215, 371–76, and 377E of the Public Health Service Act (42 U.S.C. 216, 273–274d, 274f–5); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8, and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

■ 2. In § 121.6, revise paragraph (b) to read as follows:

§ 121.6 Organ procurement.

* * * * *

(b) *HIV.* (1) Organs from individuals infected with human immunodeficiency virus (HIV) may be transplanted only into individuals who—

(i) Are infected with HIV before receiving such organ(s); and

(ii)(A) Are participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the research criteria published by the Secretary under subsection (a) of section 377E of the Public Health Service Act, as amended; or

(B) The Secretary has published, through appropriate procedures, a determination under section 377E(c) of the Public Health Service Act, as amended, that participation in such clinical research, as a requirement for transplants of organs from individuals infected with HIV, is no longer warranted.

(2) Except as provided in paragraph (b)(3) of this section, the OPTN shall adopt and use standards of quality with respect to organs from individuals infected with HIV to the extent the Secretary determines necessary to allow the conduct of research in accordance with the criteria described in paragraph (b)(1)(ii)(A) of this section.

(3) If the Secretary has determined under paragraph (b)(1)(ii)(B) of this section that participation in clinical research is no longer warranted as a requirement for transplants of organs from individuals infected with HIV, the OPTN shall adopt and use standards of quality with respect to organs from individuals infected with HIV as directed by the Secretary, consistent with 42 U.S.C. 274, and in a way that ensures the changes will not reduce the safety of organ transplantation.

* * * * *

[FR Doc. 2015–11048 Filed 5–7–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 10

[Docket No. FWS–HQ–BPHR–2014–0028; FXGO16600954000–134–FF09B30000]

RIN 1018–BA52

Addresses of Headquarters Offices

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; technical amendment.

SUMMARY: On July 29, 2014, the U.S. Fish and Wildlife Service (we) published a final rule to update the addresses of our headquarters offices in our regulations. We inadvertently omitted two necessary address changes. We make those changes in this document.

DATES: Effective May 8, 2015.

FOR FURTHER INFORMATION CONTACT: Anissa Craghead, 703–358–2445.

SUPPLEMENTARY INFORMATION: We relocated our headquarters offices from Arlington, Virginia, to Falls Church, Virginia, on July 28, 2014. To ensure regulated entities and the general public have accurate contact information for the Service's offices, on July 29, 2014, we published a final rule (79 FR 43961) to update our headquarters addresses throughout our regulations. We inadvertently omitted two necessary address changes in the regulations at 50 CFR 10.21. We make those changes in this document.

List of Subjects in 50 CFR Part 10

Exports, Fish, Imports, Law enforcement, Plants, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 10 of subchapter A of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 10—GENERAL PROVISIONS

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 16 U.S.C. 668a–d, 703–712, 742a–j–l, 1361–1384, 1401–1407, 1531–1543, 3371–3378; 18 U.S.C. 42; 19 U.S.C. 1202.

■ 2. Amend § 10.21 by revising paragraph (a) and the first sentence of paragraph (b) to read as follows:

§ 10.21 Director.

(a) Mail forwarded to the Director for law enforcement purposes should be addressed to Chief, Office of Law Enforcement, at the address provided at 50 CFR 2.1(b).

(b) Mail sent to the Director regarding permits for the Convention on International Trade in Endangered Species of Wild Fauna and Fauna (CITES), injurious wildlife, Wild Bird