ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80
RIN 2060–AS36


AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: Because EPA received adverse comment on certain elements of the Tier 3 Amendments direct final rule published on February 19, 2015, we are withdrawing those elements of the direct final rule. EPA intends to consider the comments received and proceed with a new final rule for the withdrawn elements. The remaining elements will go into effect pursuant to the direct final rule.

DATES: Effective May 5, 2015, EPA withdraws the amendments to 40 CFR 80.1453, 80.1616, and 80.1621 published at 80 FR 9078 on February 19, 2015.

FOR FURTHER INFORMATION CONTACT: Julia MacAllister, Office of Transportation and Air Quality, Assessment and Standards Division, 2000 Traverwood Drive, Ann Arbor, Michigan 48105; telephone number: 734–214–4131; email address: MacAllister.Julia@epa.gov.

SUPPLEMENTARY INFORMATION: We stated in the Tier 3 Technical Amendments direct final rule published on February 19, 2015 (80 FR 9078) that if we received adverse comment by April 6, 2015, as to any part of the direct final rule, those parts would be withdrawn by publishing a timely notice in the Federal Register. Because EPA received adverse comment, we are withdrawing the amendments that were the subject of these adverse comments and they will not take effect. Three specific provisions are being withdrawn, as described below.

First, 40 CFR 80.1453: In the Renewable Fuel Standard (RFS) Quality Assurance Program (QAP) Rule (79 FR 42078, July 18, 2014), EPA added additional product transfer document (PTD) requirements for renewable fuels that informed parties that took ownership of the renewable fuel that they would need to (a) use the fuel as it was intended, i.e., for transportation use; and, (b) incur a renewable volume obligation (RVO) if the fuel was exported. Shortly after publication of the QAP final rule, we received questions on whether these PTD requirements would apply downstream to the end users, including residential heating oil owners and people filling up their fuel tanks at fuel retail stations. EPA provides downstream end user exemptions to the PTD requirements in other fuels programs, and the direct final rule included similar exemptions for RFS PTD requirements. The words “or custody” were inadvertently added to the RFS PTD requirements and we received several comments pointing out that applying the PTD requirements to the transfer of custody of renewable fuels would be costly to industry and not beneficial to the RFS program. In this action we are withdrawing all of the changes to 40 CFR 80.1453.

Second, 40 CFR 80.1616: The direct final rule included some clarifying language for when credits expire and are reported. We received a comment advocating for small refiners and small volume refineries to be allowed to use credits past January 1, 2020—to effectively receive a small refiner- and small volume refinery-specific period of lead time before these parties must comply with the Tier 3 sulfur standards. Although it is not clear whether this comment is germane to the provisions of the direct final rule, in light of the short time frame for withdrawal of the direct final rule, we have decided to treat this as an adverse comment on the amended rulemaking provisions and we therefore are withdrawing the proposed changes to 40 CFR 80.1616.

Third, 40 CFR 80.1621: Following publication of the Tier 3 Final Rule (79 FR 23414, April 28, 2014) we were contacted by some refiners to clarify if/when small volume refineries could be disqualified, because there was language inadvertently deleted from the regulatory text as part of the Tier 3 final rule. In re-inserting this text in the direct final rule, we clarified that small volume refinery disqualification was akin to small refiner disqualification. We received adverse comment raising the issue that the new wording is confusing because it does not explicitly state exactly when and under which circumstances that disqualification could occur, and also that the term “small refinery” was used instead of the correct term “small volume refinery”. In this action we are withdrawing all changes to 40 CFR 80.1621.

EPA published a parallel proposed rule on the same day as the direct final rule. The proposed rule invited comment on the substance of the direct final rule. EPA intends to consider the comments received and proceed with a new final rule. As stated in the parallel proposal, EPA does not plan to institute a second comment period for the proposed action with respect to the provisions that are withdrawn by this notice. The amendments for which we did not receive adverse comment are not being withdrawn and will become

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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”.

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 that the OPTN determines that participation in such clinical research 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. Otherwise, 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 BW37, 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 current 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 the mandates of the HOPE Act.