Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 8, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 70

Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: February 27, 2007.

John B. Askew,

Regional Administrator, Region 7.

■ Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

■ 2. In § 52.1320(c) the table is amended under Chapter 6 by revising the entry for ''10–6.110'' to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.110	Submission of Emission Data, Emission Fees, and Process Information.	12/30/06	3/9/07 [*insert FR page number where the document begins*].	Section (3)(D), Emissions Fees, has not been approved as part of the SIP.
*	*	*	*	*

* * * * *

PART 70—[AMENDED]

■ 3. The authority citation for Part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Appendix A—[Amended]

■ 4. Appendix A to Part 70 is amended by adding paragraph (u) under Missouri to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Missouri

* * * * *

(u) The Missouri Department of Natural Resources submitted revisions to Missouri rule 10 CSR 10–6.110, ''Submission of Emission Data, Emission Fees, and Process Information'' on December 11, 2006; approval of sections (3)(D)1., (3)(D)2.E., and (3)(D)2.F. effective May 8, 2007.

* * * * *

[FR Doc. E7–4176 Filed 3–8–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 121

RIN 0906AA62

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: This Final Rule sets forth the Secretary's decision to include intestines within the definition of organs covered by the regulations governing the operations of the Organ Procurement and Transplantation

Network. The Secretary under the authority granted by section 301 of the National Organ Transplant Act, as amended, further effects a corresponding change to the definition of human organs covered in the statute with this Final Rule.

DATES: This Final Rule is effective March 9, 2007.

FOR FURTHER INFORMATION CONTACT: Jim Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION:

Adding Intestines to the Definition of Organs Covered by the Rules Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)

Based upon a review of intestinal transplants, the Secretary believes that intestines should now be included within the definition of organs covered by the rules governing the operation of the OPTN (42 CFR part 121) (hereinafter the final rule). This Final Rule sets forth the history of intestinal transplants, the factors that have persuaded the Department of the advisability of including intestines within the ambit of the regulations governing the operation of the OPTN, and the anticipated consequences of this Rule.

The first successful intestinal transplant was performed in 1989. Intestinal transplantation may be considered for patients with irreversible intestinal failure due to surgery, trauma, or acquired or congenital disease who cannot be managed through the intravenous delivery of nutrients, also referred to as total parenteral nutrition (TPN). Although intestinal transplants have been performed for years, considerable morbidity and mortality have limited widespread clinical use. Complications are frequent and include acute and chronic rejection, lymphoproliferative disease, and serious infections such as cytomegalovirus disease. For patients who received intestinal transplants in the United States from January 2000 through June 2002, one-year graft and patient survival rates were 67 percent and 81 percent respectively for adults, and 58 percent and 65 percent respectively for pediatric recipients. Despite the shortcomings, the number of candidates for intestinal transplants and the number of intestinal transplants performed annually is increasing.

The OPTN first adopted voluntary intestinal organ allocation policies and began to maintain a list of patients waiting for intestinal transplants in 1993. On December 31, 1993, only 43 candidates were listed on the intestinal transplant waiting list, compared to 169 candidates on this list on October 24, 2003. The number of intestinal transplants performed annually has more than tripled from 34 transplants in 1993 to 109 transplants in 2002. However, the volume of transplants per transplant center is relatively small. Ten transplant centers performed one or more intestinal transplants in 2002; only five of these centers performed ten or more transplants. Overall median waiting time was 319 days for patients added to the intestinal transplant waiting list in 2001.

According to the OPTN, intestinal organ allocation may include the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract as determined by the medical needs of individual patients (OPTN Policy 3.11). OPTN voluntary policies are available at *http://www.optn.org/policiesandbylaws/policies.asp*. In addition to allocation for isolated intestinal transplants, the OPTN addresses allocation of the liver-intestine combination and multiple organs.

The nature of the regulatory framework governing the operation of the OPTN underlies the importance of including intestines within the definition of organs covered by the regulations. Under the final rule, the OPTN must submit proposed policies for review and approval by the Secretary according to the requirements of 42 CFR 121.4. Upon consideration of public comments on proposed policies that are considered significant, the Secretary will determine whether to make such proposed policies enforceable in accordance with 42 CFR 121.10. Any transplant hospital that fails to comply with any allocation policy approved as enforceable by the Secretary under this process will be subject to the enforcement sanctions delineated in 42 CFR 121.10, including termination from the Medicare and Medicaid programs.

The Secretary is legally obliged, as part of his responsibilities in administering the Medicare and Medicaid programs, to require hospitals that transplant organs to comply with the rules and requirements of the OPTN as a condition of their participation in Medicare and Medicaid under 42 U.S.C. 1320b–8(a)(1)(B). Because intestines currently are not included within the regulation's definition of organs, the Secretary cannot make any intestinal allocation policy enforceable. The inclusion of intestines as covered organs under this Final Rule will allow the Secretary to take appropriate enforcement actions against a transplant hospital that fails to comply with any OPTN intestinal allocation policy if such a policy is approved by the Secretary. This enforcement authority is particularly significant given that many recipients of transplanted intestines receive such organs together with other organs covered under the regulations. It is necessary to ensure that intestinal organ allocation, whether pertaining to isolated intestinal transplants or combined/multi-organ transplants, is consistent with the goal of an equitable national system for organ allocation. Enforcing the allocation for organs currently covered under the regulations, such as livers, would be difficult when intestines are transplanted together with other such organs if an intestinal allocation is not subject to the Secretary's enforcement authority.

As the field of intestinal transplantation evolves, it will become more critical that intestinal organ allocation keeps pace with advances in the field; that policy development include performance indicators to assess whether the goals of an equitable transplant system are being achieved; that the Secretary has the authority to make those policies enforceable; and that patients and physicians have timely access to accurate data that will assist them in making decisions regarding intestinal transplantation. Upon consideration of the foregoing factors, and in order to achieve the most equitable and medically effective use of donated organs, the Secretary has determined that intestines should explicitly be added to the definition of organs covered by the OPTN regulations at 42 CFR Part 121.

Public Participation

The public was invited to respond to the Notice of Proposed Rulemaking (NPRM) which was published in the **Federal Register** on November 23, 2005 (70 FR 70765–70768). The NPRM provided for a 60-day comment period. We received a total of three comments from the public. All three comments were in support of adding intestines to the definition of organs covered by the rules governing the OPTN and encouraged coordination with the Centers for Medicare and Medicaid Services. Consequently, this Final Rule is the same as the proposed rule published on November 23, 2005.

Soliciting Public Comment as to Whether Any Other Organs Should Be Covered by the Rules Governing the Operation of the OPTN

The Secretary invited public comment as to the advisability of including any other organ within the ambit of this final rule. The comments we received did not request the inclusion of any other organ under the OPTN regulations.

Including Intestines Within the Definition of Human Organs Covered by Section 301 of NOTA

The Secretary further invited public comment on including intestines within the definition of human organs covered by section 301, as amended, of the National Organ Transplant Act (NOTA) (hereinafter section 301), which prohibits the purchase or sale of human organs for human transplantation.

Originally as enacted section 301 of NOTA (Pub. L. 98–507) defined the term ''human organ'' as ''the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin and any other human organ specified by the Secretary of Health and Human Services by regulation.'' NOTA, Public Law 98–507, Title III, section 301, 98 Stat. 2346–2347 (1984). This section was subsequently amended by Congress to include fetal organs, as well as subparts of the specified organs, by Public Law 100–607, section 407.

As set forth by statute, Congress authorized the Secretary to add additional organs to the definition of ''human organ'' covered by section 301 through rulemaking in order to include the transplantation of additional human organs. Through this Final Rule, the Secretary adds intestines to the list of human organs covered by section 301. The Secretary adds a new section to 42 CFR Part 121 to effectuate this change.

The comments we received supported adding intestines to the definition of organs covered under section 301 of NOTA and encouraged coordination with the Centers for Medicare and Medicaid Services regarding implementation of the respective but related authorities regarding organ procurement and transplantation.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive and equity effects). In addition, under the Regulatory Flexibility Act, 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 that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this Final Rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement 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. Since independent and hospital-based organ procurement organizations (OPOs) are not considered small rural hospitals because OPOs generally service large geographical areas, a regulatory flexibility analysis under the RFA and a rural impact analysis under section 1102(b) of the Act are not required.

The Secretary has also determined that this Final Rule does not meet the criteria for a major rule as defined by Executive Order 12866, as amended by Executive Order 13258, and would have no major effect on the economy or Federal expenditures. We have determined that the Final 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 and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Nor on the basis of family well-being will the provisions of this Final Rule affect the following family elements: 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 Final Rule will modify the regulations governing the OPTN and section 301 of NOTA based on legal authority.

Impact of the New Rule

This Final Rule will have the effect of including human intestines within the ambit of the regulations governing the operation of the OPTN, and will include transplanted human intestines within the changes made at section 301 of NOTA. The changes made in this Rule will authorize the Secretary to take enforcement actions against entities violating OPTN policies pertaining to the transplantation of intestines once such policies are approved as enforceable by the Secretary. In addition, individuals violating section 301 of NOTA with respect to intestinal transplants will be subject to criminal penalties.

Paperwork Reduction Act of 1995

The amendments proposed in this Rule will not impose any additional data collection requirements beyond those already imposed under the current regulations, which have been approved by the Office of Management and Budget (OMB No. 0915–0157). The currently approved data collection includes worksheets and burden for intestinal transplants.

List of Subjects in 42 CFR Part 121

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

Dated: March 9, 2007.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Approved: November 27, 2006.

Michael O. Leavitt,

Secretary.

■ Accordingly, 42 CFR part 121 is amended as set forth below:

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

Authority: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); 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. Amend § 121.1 as follows:

■ a. Amend paragraph (a) by removing the phrase ''this part apply'' and adding in its place the phrase ''this part, with the exception of § 121.13, apply.''

■ b. Redesignate paragraph (b) as paragraph (c).

■ c. Add a new paragraph (b).

The revision reads as follows:

§ 121.1 Applicability.

* * * * *

(b) The provisions of § 121.13 apply to the prohibition set forth in section 301 of the National Organ Transplant Act, as amended.

* * * * *

§ 121.2 [Amended]

■ 3. Amend the definition of ''organ'' in § 121.2 by removing the word ''or'' and by adding the phrase '', or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract)'' after the term ''pancreas.''

■ 4. Add a new § 121.13 to read as follows:

§ 121.13 Definition of Human Organ Under section 301 of the National Organ Transplant Act, as amended.

''Human organ,'' as covered by section 301 of the National Organ Transplant Act, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.

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