8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action as defined in Executive Order 12866.

9. National Technology Transfer Advancement Act

EPA approves state programs as long as they met criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a state program, to require the use of any particular voluntary consensus standard in place of another standard that meets requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply to this rule.

10. Executive Order 12988

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

11. Executive Order 12630: Evaluation of Risk and Avoidance of Unanticipated Takings

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the Executive Order.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: November 9, 2005.

Margaret M. Guerriero,

Acting Regional Administrator, Region 5.

[FR Doc. 05–23213 Filed 11–22–05; 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: Notice of proposed rulemaking.

SUMMARY: This notice sets forth the Secretary's proposal to include intestines within the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network. The Secretary further proposes a corresponding change to the definition of human organs covered by section 301 of the National Organ Transplant Act, as amended.

DATES: To be considered, comments on this proposed rule must be submitted by January 23, 2006. Subject to consideration of the comments submitted, the Department intends to publish final regulations.

ADDRESSES: You may submit comments, identified by RIN 0906AA62, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.hrsa.gov/*. Follow the instructions for submitting comments on the Agency Web site.
- E-mail: *jburdick@hrsa.gov*. Include RIN 0906AA62 in the subject line of the message.
- Fax: 301–594–6095.
- Mail: 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.
- Hand Delivery/Courier: 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.

Instructions: All submissions received must include the agency name and Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.hrsa.gov/*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857 weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m. To schedule an appointment to view public comments, phone (301) 443–7757.

FOR FURTHER INFORMATION CONTACT: Jim Burdick, M.D. at the above address; telephone number (301) 443–7577.

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 notice 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 proposal.

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 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 final rule. Under the final rule, the OPTN must submit proposed policies for review and approval by the Secretary. 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 § 121.10 of the final rule. 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 § 121.10 of the rule, 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. 42 U.S.C. 1320b–8(a)(1)(B). Because intestines are not included within the final rule's definition of organs, the Secretary cannot currently make any intestinal allocation policy enforceable. If intestines are added as covered organs under the final rule as proposed here, the Secretary could take appropriate enforcement actions against a transplant hospital for failing to comply with the OPTN's intestinal allocation policy if such a policy has been approved as enforceable by the Secretary under the process outlined above. This enforcement authority is particularly significant given that many recipients of transplanted intestines receive such organs together with other organs covered under the final rule. 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, as described in the final rule. Enforcing allocation for organs currently covered under the final rule, such as livers, would be difficult in instances in which intestines are transplanted together with such organs if 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 announces his conclusion that intestines should explicitly be added to the definition of organs covered by the final rule.

Public Participation

Additional information on the submission of comments and/or the rulemaking process can be obtained from the Director, Division of Policy Review and Coordination, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 14A–11, Rockville, Maryland 20857.

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

The Secretary also invites public comment as to the advisability of including any other organ within the ambit of the final rule. In addition to intestines, there may be other organs not currently covered under the final rule that, as a result of factors such as medical advances, a growing demand for transplantation, and concerns about equitable allocation, should be considered for inclusion under the final rule.

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

The Secretary further proposes 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. Specifically, section 301, as amended, provides as follows:

Prohibition of Organ Purchases

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) Penalties

Any person who violates subsection (a) of this section shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (a) of this section:

(1) The term ''human organ'' means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term ''valuable consideration'' does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term ''interstate commerce'' has the meaning prescribed for it by section 321(b) of Title 21.

42 U.S.C. 274e. When it originally enacted NOTA, Congress defined the term ''human organ,'' within the

meaning of this section 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, Pub. L. 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. Pub. L. 100–607, Title IV, section 407, 102 Stat. 3116 (1988).

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 within section 301's prohibition. Through this notice, the Secretary proposes to add intestines to the list of human organs covered by section 301. The Secretary proposes adding a new section to part 121 to effectuate this addition, which section 301 authorizes the Secretary to make by rulemaking.

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 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 proposed rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the proposed 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 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 proposed rule would modify the regulations governing the OPTN and section 301 of NOTA based on legal authority.

Impact of the New Rule

This proposed rule would have the effect of including transplanted human intestines within the ambit of the regulations governing the operation of the OPTN, and would include transplanted human intestines within the prohibition set forth at section 301 of NOTA. If implemented, the proposals set forth in this rule would 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, if this proposal is implemented, individuals violating section 301 of NOTA with respect to intestinal transplants would be subject to criminal penalties.

Paperwork Reduction Act of 1995

The amendments proposed in this notice of proposed rulemaking will not impose any additional data collection requirements beyond those already imposed under the current final rule, 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 1, 2005.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Approved: May 20, 2005.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register November 18, 2005.

Accordingly, 42 CFR part 121 is proposed to be 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. Revise paragraph (a) by replacing the phrase ''this part apply'' with 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.

* * * * *

3. Revise the definition of ''organ'' in § 121.2 to read as follows:

§ 121.2 Definitions.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, or intestine.

* * * * *

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 (or any subpart thereof).

[FR Doc. 05–23149 Filed 11–22–05; 8:45 am]

BILLING CODE 4160–15–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

45 CFR Part 1182

RIN 3137–AA17

Institute of Museum and Library Services; Implementation of the Privacy Act of 1974

AGENCY: Institute of Museum and Library Services (IMLS), NFAH.

ACTION: Proposed rule.

SUMMARY: The Institute of Museum and Library Services (Institute) in publishing a proposed rule setting forth regulations under the Privacy Act of 1974 and conforming to the President's memorandum of June 1, 1998—Plain Language in Government Writing. These regulations establish procedures by which an individual may determine whether a system of records maintained by the Institute contains a record pertaining to him or her; gain access to such records; and request correction or amendment of such records. These regulations also establish exemptions from certain Privacy Act requirements for all or part of certain systems or records maintained by the Institute.

DATES: Comments are invited and must be received by no later than December 23, 2005.

ADDRESSES: Address all comments concerning this proposed rule to Nancy E. Weiss, General Counsel, Institute of Museum and Library Services, 1800 M Street, NW., 9th Floor, Washington, DC 20036. Submit electronic comments to *nweiss@imls.gov.* Telephone: (202) 653–4784. Facsimile: (202) 653–4625.

FOR FURTHER INFORMATION CONTACT: Nancy E. Weiss, General Counsel, Institute of Museum and Library Services, 1800 M Street, NW., Ninth Floor, Washington, DC 20036. E-mail: *nweiss@imls.gov.* Telephone: (202) 653–4787. Facsimile: (202) 653–4625.

SUPPLEMENTARY INFORMATION: The Institute operates as part of the National Foundation on the Arts and the Humanities under the National Foundation on the Arts and the Humanities Act of 1965, as amended (20 U.S.C. 951 *et seq.*). The corresponding regulations published at 45 CFR Chapter XI, Subchapter A apply to the entire Foundation, while the regulations published at 45 CFR Chapter XI, Subchapter E apply only to the Institute.

This proposed rules adds Privacy Act regulations to Subchapter E (45 CFR part 1182), replacing the existing regulations in Subchapter A (45 CFR part 1115) with regard to the Institute. The new regulations provide additional detail concerning several provisions of the Privacy Act, and are intended to increase understanding of the Institute's Privacy Act policies. The Institute is authorized to propose the new regulations under 5 U.S.C. 552a(f) of the Privacy Act.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

The regulatory repeal proposed in this rulemaking eliminates outdated regulations and makes technical amendments to reflect Congress' reauthorization of the Institute of Museum and Library Services under The Museum and Library Services Act of 2003, Public Law 108–81 (September 25, 2003). These changes are proposed to ensure that all regulations governing provision of grants made by the Institute are consistent with current statutory guidance and agency practice. The public is invited to make substantive comment on any of these proposed changes.

Comments should be submitted in writing to the address indicated in the **ADDRESSES** section of this document. All comments received will be available upon request for public inspection at Institute of Museum and Library Services, 1800 M Street, NW., Ninth Floor, Washington, DC 20036. All written comments received by the date indicated in the **DATES** section of this document and all other relevant information in the record will be carefully assessed and fully considered prior to publication of the final rule. Any information considered to be confidential must be so identified and submitted in writing. We will not consider comments submitted anonymously. However, if you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment.

II. Matters of Regulatory Procedure

Regulatory Planning and Review (E.O. 12866)

Under Executive Order 12866, the Institute must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Proposed rules would add Privacy Act regulations to subchapter E (45 CFR part 1182), replacing the existing regulations in Subchapter A (45 CFR part 1115) with regard to the Institute. The new regulations provide additional detail concerning several provisions of the Privacy Act, and are intended to increase understanding of the Institute's Privacy Act policies. As such, it does not impose a compliance burden on the economy generally or on any person or entity. Accordingly, this rule is not a ''significant regulatory action'' from an economic standpoint, and it does not otherwise create any inconsistencies or budgetary impacts to any other agency or Federal Program.

Regulatory Flexibility Act

Because this proposed rule would add Privacy Act regulations to Subchapter E (45 CFR part 1182), replacing the existing regulations in Subchapter A (45 CFR part 1115) with regard to the Institute, the Institute has determined in Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) review that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule is exempt from the requirements of the Paperwork Reduction Act, since it adds Privacy Act regulations to Subchapter E (45 CFR part 1182), replacing the existing regulations in Subchapter A (45 CFR part 1115) with regard to the Institute. An OMB form 83–1 is not required.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local,