

US EPA ARCHIVE DOCUMENT

Executive Order 13175 Consultation and Coordination With Indian Tribal Governments

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13132 Federalism

This proposed action also does not have federalism implications because it does not have substantial direct effects on the states, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). Redesignation is an action that merely affects the status of a geographical area, does not impose any new requirements on sources, or allows a state to avoid adopting or implementing other requirements, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13045 Protection of Children From Environmental Health and Safety Risks

This proposed rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

National Technology Transfer Advancement Act

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Redesignation is an action that affects the status of a geographical area but does not impose any new requirements on sources. 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.

Paperwork Reduction Act

This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen oxides, Ozone, Volatile organic compounds.

40 CFR Part 81

Air pollution control, Environmental protection, National parks, Wilderness areas.

Dated: November 15, 2005.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 05-23221 Filed 11-22-05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-8001-4]

Michigan: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Michigan has applied to the EPA for final authorization of the changes to its hazardous waste management program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for final authorization and is proposing to authorize the state's changes through this proposed final action.

DATES: Written comments must be received on or before December 23, 2005.

ADDRESSES: Send written comments to Ms. Judy Feigler, Michigan Regulatory Specialist, U.S. Environmental Protection Agency, Waste, Pesticides and Toxics Division (DM-7J), 77 W. Jackson Blvd., Chicago, Illinois 60604, phone number: (312) 886-4179. We must receive your comments by December 23, 2005. You can view and copy Michigan's application from 9 a.m. to 4 p.m. at the following addresses: Waste Management Division, Michigan Department of Environmental Quality, Constitution Hall—Atrium North,

Lansing, Michigan (mailing address P.O. Box 30241, Lansing, Michigan 48909), contact Ronda Blayer (517) 353-9548; and EPA Region 5, contact Judy Feigler at the following address.

FOR FURTHER INFORMATION CONTACT: Judy Feigler, Michigan Regulatory Specialist, U.S. EPA, DM-7J, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886-4179.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the federal program. As the federal program changes, states must change their programs and ask EPA to authorize the changes. Changes to state programs may be necessary when federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, states must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Michigan's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we propose to grant Michigan final authorization to operate its hazardous waste management program with the changes described in the authorization application. Michigan has responsibility for permitting treatment, storage, and disposal facilities (TSDFs) within its borders (except in Indian country) and for carrying out the aspects of the RCRA described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New federal requirements and prohibitions imposed by federal regulations that EPA promulgates under the authority of HSWA take effect in authorized states before they are authorized for the requirements. Thus, EPA will implement those requirements and prohibitions in Michigan, including issuing permits, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

This decision means that a facility in Michigan subject to RCRA will now have to comply with the authorized state requirements (listed in section F of

this notice) instead of the equivalent federal requirements in order to comply with RCRA. Michigan has enforcement responsibilities under its state hazardous waste management program for violations of such program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, the authority to:

- Do inspections, and require monitoring, tests, analyses or reports;
- Enforce RCRA requirements and suspend or revoke permits; and
- Take enforcement actions regardless of whether the state has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which Michigan is being authorized by today's action are already effective, and are not changed by today's action.

D. What Happens if EPA Receives Comments That Oppose This Action?

If EPA receives comments that oppose this authorization, we will address all public comments in a later **Federal Register**. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

E. What Has Michigan Previously Been Authorized for?

Michigan initially received final authorization on October 16, 1986, effective October 30, 1986 (51 FR 36804–36805) to implement the RCRA hazardous waste management program. We granted authorization for changes to Michigan's program on November 24, 1989, effective January 23, 1990 (54 FR 48608); on January 24, 1991, effective June 24, 1991 (56 FR 18517); on October 1, 1993, effective November 30, 1993 (58 FR 51244); on January 13, 1995,

effective January 13, 1995 (60 FR 3095); on February 8, 1996, effective April 8, 1996 (61 FR 4742); on November 14, 1997, effective November 14, 1997 (62 FR 61775); on March 2, 1999, effective June 1, 1999 (64 FR 10111); and on July 31, 2002, effective July 31, 2002 (67 FR 49617).

F. What Changes Are We Authorizing With Today's Action?

On September 7, 2005, Michigan submitted a complete program revision application seeking authorization of its changes in accordance with 40 CFR 271.21. We now make a final decision, subject to receipt of written comments that oppose this action, that Michigan's hazardous waste management program revision satisfies all requirements necessary to qualify for final authorization. Therefore, we propose to grant Michigan final authorization for the following program changes:

PROGRAM REVISIONS BASED ON FEDERAL RCRA CHANGES

Description of federal requirement	Checklist No., if relevant	Federal Register date and page (and/or RCRA statutory authority)	Analogous state authority
HSWA Codification Rule; Household Waste (Resource Recovery Facilities), Corrective Action Management Units and Temporary Units.	17C 121	July 15, 1985, 50 FR 28702 February 16, 1993, 58 FR 8658	R 299.9204(2)(a) and (2)(a)(i)–(ii). R 299.9102(s) and (cc), R 299.9103(r), R 299.9105(c)(vii), R 299.9105(t), R 299.9107(j), R 299.9311, R 299.9413, R 299.9519(9), R 299.9601(1), (2)(k) and (l) and (3)(a), R 299.9627, R 299.9629(3)(a) and (b), R 299.9635(3), R 299.9636, and R 299.11003(1)(u).
Waste Water Treatment Sludges from Metal Finishing Industry; 180-day Accumulation Time.	184	March 8, 2000, 65 FR 12378	R 299.9306(1)(d) and (7)–(10).
Organobromine Production Waste and Petroleum Refining Process Waste: Technical Correction.	187	June 8, 2000, 65 FR 36365	R 299.9220 and R 299.11003(1)(u).
NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combusters.	188, 188.1, 188.2 ..	July 10, 2000, 65 FR 42292; May 14, 2001, 66 FR 24270; July 3, 2001, 66 FR 35087.	R 299.9230(2) and (3); R 299.9519(5)(j)(v); R 299.9623(2), (3)(b) and (11); and R 299.11003(1)(n).
Chlorinated Aliphatics Production Wastes; Land Disposal Restrictions for Newly Identified Wastes; and CERCLA Hazardous Substance Designation and Reportable Quantities.	189	November 8, 2000, 65 FR 67068	R 299.9222, R 299.9311, R 299.9413, R 299.9627, and R 299.11003(1)(j) and (u).
Deferral of Phase IV Standards for PCBs as a Constituent Subject to Treatment in Soil.	190	December 26, 2000, 65 FR 81373	R 299.9311, R 299.9413, R 299.9627, and R 299.11003(1)(u).
Storage, Treatment, Transportation and Disposal of Mixed Wastes.	191	May 16, 2001, 66 FR 27218	R 299.9101(q), R 299.9102(d) and (z), R 299.9103(d) and (k), R 299.9104, R 299.9105(b), (j), (k), (v), (w), (z) and (aa), R 299.9203, R 299.9822(2)–(14), R 299.9823(2)–(4) and (6)–(12).
Mixture and Derived-From Rule Revisions.	192A	May 16, 2001, 66 FR 27266	R 299.9203(1)(c), (3), (7) and (8).
Land Disposal Restrictions Correction ..	192B	May 16, 2001, 66 FR 27266	R 299.9311, R 299.9413, R 299.9627, and R 299.11003(1)(u).
Change of EPA Mailing Address; Additional Technical Amendments and Corrections.	193	June 28, 2001, 66 FR 34374	R 299.11005(2).

PROGRAM REVISIONS BASED ON FEDERAL RCRA CHANGES—Continued

Description of federal requirement	Checklist No., if relevant	Federal Register date and page (and/or RCRA statutory authority)	Analogous state authority
Correction to the Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules.	194	October 3, 2001, 66 FR 50332	R 299.9203(1)(c) and (7)(c).
Inorganic Chemical Manufacturing Wastes Information and Listing.	195, 195.1	November 20, 2001, 66 FR 58258; April 9, 2002, 67 FR 17119.	R 299.9204(2)(o), R 299.9222, R 299.9311, R 299.9413, R 299.9627, and R 299.11003(1)(j) and (u).
CAMU Amendments	196	January 22, 2002, 67 FR 2962	R 299.9102(s) and (t), R 299.9107(j), R 299.9635, R 299.9638, and R 299.9639.
Hazardous Air Pollutant Standards for Combusters: Interim Standards.	197	February 13, 2002, 67 FR 6792	R 299.9504(4), (15) and (20), R 299.9508(1)(b), R 299.9601(2)(i) and (7), R 299.9623, R 299.9640, R 299.9808(4), (7) and (9), R 299.11003(1)(v).
Hazardous Air Pollutant Standards for Combusters; Corrections.	198	February 14, 2002, 67 FR 6968	R 299.9519(5)(j)(v), R 299.9808(2), (3), (4), (7) and (9); and R 299.11003(1)(r).
Vacatur of Mineral Processing Spent Materials Being Reclaimed as Solid Wastes and TCLP Use with MGP Waste.	199	March 13, 2002, 67 FR 11251	R 299.9202(1)(b)(iii), R 299.9204(1)(v), and R 299.9212(4).
Zinc Fertilizers Made From Recycled Hazardous Secondary Materials.	200	July 24, 2002, 67 FR 48393	R 299.9204(1)(x) and (y), R 299.9311, R 299.9413, R 299.9627, R 299.9801(3) and (5), and R 299.11003(1)(u).
Land Disposal Restrictions: National Treatment Variance to Designate New Treatment Subcategories for Radioactively Contaminated Cadmium-, Mercury-, and Silver-Containing Batteries.	201	October 7, 2002, 67 FR 48393	R 299.9311, R 299.9413, R 299.9627, and R 299.11003(1)(u).
NESHAP: Standards for Hazardous Air Pollutants for Hazardous Waste Combusters: Corrections.	202	December 19, 2002, 67 FR 77687	R 299.9504(4) and (15) and R 299.9508(1)(b), R 299.9623(8), and R 299.9808(7) and (9).
Recycled Used Oil Management Standards.	203	July 30, 2003, 68 FR 44659	R 299.9205(8), R 299.9809 (1)(e) and (2)(p), and R 299.9815(1)(b) and (3)(f).

STATE-INITIATED MODIFICATIONS

State requirement	Effective date	Federal analog
MAC R 299.9205(4)	October 15, 1996	40 CFR 261.5 and 262.34.
MAC R 299.9206(3)	September 11, 2000	40 CFR 261.6(a)(3).
MAC R 299.9206(3)(g)	September 11, 2000	40 CFR 261.6(1)(2).
MAC R 299.9207(3)	June 21, 1994	40 CFR 261.7(b)(1)(i).
MAC R 299.9212(1), (2), and (3)	October 15, 1996	40 CFR 261.21, 261.22, and 261.23.
MAC R 299.9215(3)	April 20, 1988	40 CFR 261.21(c).
MAC R 299.9303(4)	September 22, 1998	40 CFR 262.12(b) and 270.11.
MAC R 299.9304(2)(h) and (4)(c)	October 15, 1996	40 CFR 262.20.
MAC R 299.9304(6)	October 15, 1996	None.
MAC R 299.9306(1)(e) and (f)	October 15, 1996	40 CFR 262.34(a)(1).
MAC R 299.9307(5)–(7)	September 22, 1998	40 CFR 262.40(c).
MAC R 299.9401	October 15, 1996	40 CFR 263.10.
MAC R 299.9404	October 15, 1996	40 CFR 263.12.
MAC R 299.9410(1) and (3)	October 15, 1996	40 CFR 263.30 and 263.31.
MAC R 299.9503(1)(i) and (k) and (5)	October 15, 1996	40 CFR 262.34.
MAC R 299.9508(1)(f)	October 15, 1996	40 CFR 270.14(b)(17).
MAC R 299.9514(1) and (2)(c)	September 22, 1998	40 CFR 124.12.
MAC R 299.9516(3)	October 15, 1996	40 CFR 270.50.
MAC R 299.9611(4)	October 15, 1996	None.
MAC R 299.9629(3)(a)(ii) and (iii) and (3)(b)(ii) and (iii)	September 11, 2000	40 CFR 264.90(a) and 264.101(b).
MAC R 299.9633	October 15, 1996	40 CFR 260.10, definition of “treatment”.
MAC R 299.9701(2) (removal) and (3) renumbered as (2)	September 11, 2000	40 CFR 264.140(a) and (c).
MAC R 299.9713(6) and (7)	October 15, 1996	40 CFR 264.101(b).
MAC R 299.11004(4)	September 11, 2000	40 CFR part 263.
MAC R 299.11007(2)	September 11, 2000	None.
MAC R 299.11008(2)	September 11, 2000	None.

G. Where Are the Revised State Rules Different from the Federal Rules?

Michigan hazardous waste management regulations are more stringent than the corresponding federal regulations in a number of different areas. The more stringent provisions are being recognized as a part of the federally-authorized program and are federally enforceable. More stringent provisions in the state's authorization application include, but are not limited to, the following:

1. At MAC R 299.9203(7)(a) and (c), Michigan's exclusion differs from the corresponding Federal counterpart at 40 CFR 261.3(g)(2)(i) in that the exclusion only applies to mixtures generated as a result of a cleanup conducted at the individual site of generation pursuant to parts 31, 111, 201, or 213 of Michigan's Act 451 (1994 PA 451, MCL 324.101, known as the natural resources and environmental protection act), or CERCLA.

2. At R 299.9306(7)(d)(i) and (ii) and (g), Michigan's rules contain containment, inspection, recordkeeping and emergency requirements that are not found in the Federal counterpart at 40 CFR 262.34(g)(4)(i)(A) and (B) and (g)(4)(v), respectively.

3. At R 299.9307(7)(d)(i)(C), Michigan does not allow containment buildings, as does 40 CFR 262.34(g)(4)(i)(C).

4. At R 299.9639(5)(e), Michigan does not allow permits as a shield as does the Federal counterpart at 40 CFR § 264.555(e)(5).

We consider the following state requirements to be beyond the scope of the Federal program, though this list may not be exhaustive:

At R 299.9104 and R 299.9203, Michigan regulates more hazardous wastes than the Federal counterpart at 40 CFR 266.210. The hazardous wastes that are regulated by Michigan but not by EPA are broader-in-scope requirements.

Broader-in-scope requirements are not part of the authorized program and EPA cannot enforce them. Although you must comply with these requirements in accordance with state law, they are not RCRA requirements.

H. Who Handles Permits After the Authorization Takes Effect?

Michigan will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization, until they expire or are terminated. We will not issue any more

new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Michigan is not yet authorized.

I. How Does Today's Action Affect Indian Country (18 U.S.C. 1151) in Michigan?

Michigan is not authorized to carry out its hazardous waste program in Indian country within the state, as defined in 18 U.S.C. 1151. This includes:

1. All lands within the exterior boundaries of Indian reservations within the State of Michigan;

2. Any land held in trust by the U.S. for an Indian tribe; and

3. Any other land, whether on or off an Indian reservation that qualifies as Indian country.

EPA will continue to implement and administer the RCRA program in Indian country. It is EPA's long-standing position that the term "Indian lands" used in past Michigan hazardous waste approvals is synonymous with the term "Indian country." *Washington Dep't of Ecology v. U.S. EPA*, 752 F.2d 1465, 1467, n.1 (9th Cir. 1985). See 40 CFR 144.3 and 258.2.

J. What Is Codification and Is EPA Codifying Michigan's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the state's statutes and regulations that comprise the state's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized state rules in 40 CFR part 272. Michigan's rules, up to and including those revised October 19, 1991, have previously been codified through incorporation-by-reference effective April 24, 1989 (54 FR 7421, February 21, 1989); as amended effective March 31, 1992 (57 FR 3724, January 31, 1992). We reserve the amendment of 40 CFR part 272, subpart X, for the codification of Michigan's program changes until a later date.

K. Statutory and Executive Order Reviews

This proposed rule only authorizes hazardous waste requirements pursuant to RCRA 3006 and does not impose requirements other than those already imposed by state law (see

SUPPLEMENTARY INFORMATION, Section A. Why Are Revisions to State Programs Necessary?; and Section C. What Is the Effect of Today's Authorization Decision?). Therefore, this rule complies

with applicable executive orders and statutory provisions as follows:

1. Executive Order 18266: Regulatory Planning Review

The Office of Management and Budget has exempted this rule from its review under Executive Order 12866 (58 FR 51735, October 4, 1993).

2. Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

3. Regulatory Flexibility Act

After considering the economic impacts of today's rule on small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), I certify that this rule will not have a significant economic impact on a substantial number of small entities.

4. Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

5. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 19, 1999) does not apply to this rule because it will not have federalism implications (*i.e.*, substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government).

6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this rule because it will not have tribal implications (*i.e.*, substantial direct effects on one or more Indian tribes, or on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.)

7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant and it is not based on environmental health or safety risks.

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