federal register

Friday
March 24, 1989

Part II

Environmental Protection Agency

40 CFR Parts 22 and 259

Standards for the Tracking and Management of Medical Waste; Interim Final Rule and Request for Comments

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 22 and 259

[FRL-3512-5]

Standards for the Tracking and Management of Medical Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule and request for Comments.

SUMMARY: On November 1, 1988, the Medical Waste Tracking Act of 1988 (MWTA) was signed into law. Among other things, this Act requires the U.S. Environmental Protection Agency (EPA) to establish a two-year demonstration program for tracking medical waste generated in States subject to the program, even if the wastes are ultimately taken out of the State for treatment or disposal. The regulations establishing this program must include a list of medical wastes to be tracked and minimum standards for segregation from other wastes, packaging, and labeling before transport to treatment and/or disposal facilities. Facilities that incinerate medical waste on-site are also subject to certain reporting requirements. The MWTA designates Connecticut, New Jersey, New York, and those States bordering the Great Lakes as being subject to the demonstration tracking program. Under certain conditions, however, these designated States may opt out of the program. In addition, any other State may petition the Agency to participate in the program.

These regulations apply to medical waste generators in States that participate in the program. In addition, they apply to other handlers (transporters, transfer facilities, and treatment or disposal facilities) who manage regulated medical wastes that originated in a State that participates in the demonstration tracking program.

The Act also requires EPA to submit a final report and two interim reports to Congress discussing the program's overall success and the information obtained from the program to date. The results of the demonstration program will assist Congress in determining whether or not the provisions of the medical waste tracking program should be extended nationwide.

Today's interim final rule specifies the procedures and criteria under which States may petition in or opt out of the demonstration program. It also lists the wastes identified by EPA as medical wastes for the purposes of the Medical Waste Tracking Act and sets forth the regulations and standards for implementing the demonstration tracking program under the Act. In addition, today's rule requests public comment on the regulations presented here.

DATES: The regulation is effective June 22, 1989.

Compliance— The effective date for the demonstration program is June 22, 1989 through June 22, 1991. Transporters must notify EPA prior to collecting or transporting regulated medical waste generated in a Covered State during the demonstration program. Notification should be received by the Agency prior to the effective date of today's regulations. Notice for States petitioning in and opting out of the demonstration program must be submitted by April 24, 1989.

Comments—Members of the public may submit comments on today's rule until May 23, 1989. Comments must be submitted in triplicate to the Resource Conservation and Recovery Act (RCRA) Docket at the address below.

ADDRESSES: The docket for this rulemaking (Docket No. F-89-MTPF-FFFFF) is located at the U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Public comments should be sent to this address and should include the above-referenced docket number. The docket is open from 9:30 a.m. to 3:30 p.m., Monday through Friday, except for Federal holidays. You may make an appointment to review docket materials by calling (202) 475-9327. You may copy a maximum of 100 pages of material from any one regulatory docket at no cost. Additional copies cost $0.15 per page.

States' notices to petition in or opt out of the program should be sent to the Administrator of EPA, 401 M Street SW., Washington, DC 20460, with a copy to the Chief, Waste Characterization Branch (OS-332), at the same address.

FOR FURTHER INFORMATION CONTACT: The toll-free RCRA/Superfund Hotline at (800) 424-9346 or (202) 382-3000 in Washington, DC, or Michael Petruska, Office of Solid Waste, U.S. Environmental Protection Agency, 401 M Street SW., Room S-242 Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. Authority
II. Background
A. The Medical Waste Tracking Act of 1988
B. Subtitle J of RCRA
C. Previous Agency Action Concerning Infectious Waste
D. Consultation and Public Comment
1. Consultation with States and Other Parties
2. Consultation with International Joint Commission
III. Future Agency Action
A. Actions Under Other Agency Programs
B. Reports to Congress
C. Regulatory Assessment
D. Educational Activities
E. Program Evaluation
IV. Overview of the Demonstration Program Tracking System
A. Uniform Tracking Form
B. How the Tracking System Operates
1. Generator Responsibilities
2. Transporter and Transfer Facility Responsibilities
3. Treatment and Disposal Facility Responsibilities
V. Analysis of the Rule—Part 259 Standard for the Tracking and Management of Medical Waste
A. Subpart A— General
1. Waste Generated in a Covered State
2. Effective Dates and Duration of the Program
B. Subpart B—Definitions
1. Storage
2. Treatment
3. Generator
C. Subpart C—Covered States
1. Connecticut, New Jersey, and New York
2. Great Lakes States
3. Other States
D. Subpart D—Regulated Medical Waste
1. Definition of Solid Waste
2. Definition of Medical Waste
3. Definition of Regulated Medical Waste
4. Determination to Exclude Certain Waste Types
5. Unregulated Medical Wastes
6. Mixtures
7. Exclusions and Exemptions
8. Relationship to Previous EPA Definition
E. Subpart E—Pre-transport Requirements
1. Segregation Requirements
2. Packaging Requirements
3. Storage Requirements
4. Decontamination Standards for Reusable Containers
5. Labeling Requirements
6. Marking (Identification) Requirements
F. Subpart F—Generator Requirements
1. Applicability and General Requirements
2. Requirement to Use Transporters who Have Notified EPA
3. Acquisition and Use of the Tracking Form
4. Use of Logs by Generators of Less Than 50 Pounds Per Month
5. Exports of Regulated Medical Waste
6. Recordkeeping
7. Exception Reporting
8. Additional Reporting
G. Subpart G—On-site Incinerator Requirements
1. Recordkeeping
2. Reporting
H. Subpart H—Transporter Requirements
1. Transporter Notification
2. Vehicle Requirements
3. Transporter Tracking Form Requirements
4. Acceptance of Medical Waste
5. Consolidation or Remanifesting of Regulated Medical Waste
6. Transporter Recordkeeping and Reporting Requirements
7. Delivery of Regulated Medical Waste Outside the United States

I. Subpart I—Treatment, Destruction, and Disposal Facilities
1. Applicability
2. Types of Treatment, Destruction, and Disposal Facilities
3. Use of the Tracking Form
4. Tracking Form Discrepancies
5. Recordkeeping Requirements
6. Treatment, Destruction, and Disposal of Medical Waste
J. Subpart J—Rail Shipments of Regulated Medical Waste
VI. Relationship to Other EPA Programs
A. Other Subtitles of RCRA
1. Subtitle C—Hazardous Waste Management
2. Subtitle D—State or Regional Solid Waste Plans
3. Subtitle G—Miscellaneous Provisions
B. CERCLA
C. Clean Air Act
D. Water Pollution Control
1. Clean Water Act
2. Marine Plastic Pollution Research and Control Act of 1987
3. Marine Protection, Research and Sanctuaries Act of 1972
4. United States Public Vessel Medical Waste Anti-Dumping Act of 1988
5. Shore Protection Act of 1988
E. EPA Research Activities
F. EPA's Office of International Activities
VII. Relationship to other Federal Regulatory Programs
A. Nuclear Regulatory Commission (NRC)
1. Labeling
2. Manifesting
3. Packaging
4. Limitation of Generator's Disposal Options
B. United States Department of Agriculture (USDA)
1. Animals with Communicable Diseases
2. Veterinary Biological Products
C. Department of Labor (DOL)—Occupational Safety and Health Administration (OSHA)
D. Department of Health and Human Services (DHHS)
1. Food and Drug Administration (FDA)
2. Public Health Service (PHS)
3. Health Care Financing Administration (HCFA)
E. Department of Transportation (DOT)
1. Hazardous Materials Shipments
2. MARPOL 73/78
VIII. Federal Facilities
IX. Joint Federal and State Implementation
A. Regulatory Authority
B. Enforcement Authority
X. Regulatory Impacts
A. Executive Order 12291—Regulatory Impact
1. Cost Methodology
2. Direct Compliance Costs
3. Characterizing the Regulated Community
4. Medical Waste Generation Rates
5. Existing Management Practices
6. Tracking System Requirements
7. Generators of Less Than 50 Pounds
8. Incinerator Reporting
9. Packaging
10. Existing and Proposed Medical Waste Regulations
11. Results
12. Sensitivity Analysis
13. Benefits
B. Regulatory Flexibility Act
C. Paperwork Reduction Act

I. Authority

These regulations are issued under the authority of sections 2002, 11001, 11002, 11003, 11004, 11005, 11010, and 11011 of the Solid Waste Disposal Act of 1970, as amended by the Medical Waste Tracking Act of 1988, 42 U.S.C. 6992 *et seq.*

II. Background

A. The Medical Waste Tracking Act of 1988

The Medical Waste Tracking Act (MWTA) of 1988 was signed into law on November 1, 1988. This Act amends the Solid Waste Disposal Act, commonly referred to as the Resource Conservation and Recovery Act (RCRA), to require the Administrator of the Environmental Protection Agency (EPA) to promulgate regulations that establish a demonstration tracking system for medical waste.

The MWTA was enacted as a response to public concern over the degradation of shoreline areas, particularly in Connecticut, New Jersey, and New York, from washups of sewage and other waste. The medical debris raising the most concern were wastes, such as needles, syringes, blood bags, bandages, and vials. See 134 Cong. Rec. S 10737 (August 3, 1988). There were also reports of other incidents of careless management of medical waste; for instance, by disposal into open dumpsters, creating additional concern for public safety. 134 Cong. Rec. H 9536 (October 4, 1988).

The result of the beach washups was the closure of beaches, economic losses in affected shore communities, and public concern over the health hazards associated with medical wastes and the general degradation of the shore environment. 134 Cong. Rec. S 19745 (August 4, 1988) and 134 Cong. Rec. H 9536 (October 4, 1988). Improper management of medical waste raised concerns over the health risks posed by the infectious character of the waste, the physical hazard posed by the wastes, particularly needles and other sharps, and the aesthetic degradation of the vulnerable shoreline environment. 134 Cong. Rec. S 10738 (August 3, 1988). Congress found the appearance of medical waste on the beaches to be repugnant, intolerable, and unacceptable. 134 Cong. Rec. S 10739–S 10745 (August 4, 1988).

The MWTA was enacted against this background of health and environmental concerns. The Act was intended to be a first step in addressing these problems. 134 Cong. Rec. S 15327 (October 7, 1988). The Act establishes a "cradle to grave" system to track medical waste generated in the regions most affected by medical waste mismanagement problems to its final destination. The Act thus is intended to address the medical waste mismanagement problem in several ways. First, the tracking system is designed to be implemented quickly so that, to the extent the program controls sources contributing to washups, washups of medical waste in the summer of 1989 will be avoided. *Id.* Second, the bill was designed to prevent careless management of the waste by establishing tracking and storage requirements and subjecting violators to administrative, civil, and criminal penalties. 134 Cong. Rec. S 15328 (October 7, 1988). Third, the Act was intended to provide, through the tracking system, assurance that the medical waste generated in the affected States in fact reaches its intended destination, and a mechanism for tracing incidents of improper disposal to responsible parties. 134 Cong. Rec. H 9537 (October 4, 1988) and 134 Cong. Rec. S 10745 (August 3, 1988). As noted by the sponsor of the bill, the tracking system is intended to work as a "burglar alarm," alerting EPA and State officials whenever waste has not reached its intended destination and leaving a paper trail that will lead to the violators. 134 Cong. Rec. H 9536 (October 4, 1988). Finally, the legislation is intended to provide information to Congress on the effectiveness of the program and whether and how a broader program should be developed. 134 Cong. Rec. S 10743 (August 3, 1988).

EPA has developed a regulatory program that should accomplish a number of objectives set forth in the Act. Under today's regulations, increased quantities of medical waste will be packaged securely. This will reduce the chances of waste handlers and the public being exposed to medical waste. Although currently available data suggest that medical waste does not generally pose a significant potential for disease transmission, proper packaging will reduce physical hazards (i.e., needle sticks, etc.), and it will help ensure that any health risks are minimized.

Second, due to the presence of labels, marking tags, and a uniform tracking form, medical waste will be more easily identified. This should serve as a deterrent to careless or otherwise improper waste management, and it will help identify parties who do not manage their waste properly. Better identification of medical waste is also