SUBCHAPTER X—DEMONSTRATION MEDICAL WASTE TRACKING PROGRAM

§ 6992. Scope of demonstration program for medical waste

(a) Covered States

The States within the demonstration program established under this subchapter for tracking medical wastes shall be New York, New Jersey, Connecticut, the States contiguous to the Great Lakes and any State included in the program through the petition procedure described in subsection (c), except for any of such States in which the Governor notifies the Administrator under subsection (b) that such State shall not be covered by the program.

(b) Opt out

- (1) If the Governor of any State covered under subsection (a) which is not contiguous to the Atlantic Ocean notifies the Administrator that such State elects not to participate in the demonstration program, the Administrator shall remove such State from the program.
- (2) If the Governor of any other State covered under subsection (a) notifies the Administrator that such State has implemented a medical waste tracking program that is no less stringent than the demonstration program under this subchapter and that such State elects not to participate in the demonstration program, the Administrator shall, if the Administrator determines that such State program is no less stringent than the demonstration program under this subchapter, remove such State from the demonstration program.
- (3) Notifications under paragraphs (1) or (2) shall be submitted to the Administrator no later than 30 days after the promulgation of regulations implementing the demonstration program under this subchapter.

(c) Petition in

The Governor of any State may petition the Administrator to be included in the demonstration program and the Administrator may, in his discretion, include any such State. Such petition may not be made later than 30 days after promulgation of regulations establishing the demonstration program under this subchapter, and the Administrator shall determine whether to include the State within 30 days after receipt of the State's petition.

(d) Expiration of demonstration program

The demonstration program shall expire on the date 24 months after the effective date of the regulations under this subchapter.

(Pub. L. 89–272, title II, §11001, as added Pub. L. 100–582, §2(a), Nov. 1, 1988, 102 Stat. 2950.)

§6992a. Listing of medical wastes

(a) List

Not later than 6 months after November 1, 1988, the Administrator shall promulgate regulations listing the types of medical waste to be tracked under the demonstration program. Except as provided in subsection (b), such list shall include, but need not be limited to, each of the following types of solid waste:

- (1) Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.
- (2) Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy.
- (3) Waste human blood and products of blood, including serum, plasma, and other blood components.
- (4) Sharps that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades.
- (5) Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.
- (6) Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.
- (7) Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.
- (8) Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats.
- (9) Discarded medical equipment and parts that were in contact with infectious agents.
- (10) Biological waste and discarded materials contaminated with blood, excretion, excudates ¹ or secretion from human beings or animals who are isolated to protect others from communicable diseases.
- (11) Such other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment.

(b) Exclusions from list

The Administrator may exclude from the list under this section any categories or items described in paragraphs (6) through (10) of subsection (a) which he determines do not pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

(Pub. L. 89–272, title II, §11002, as added Pub. L. 100–582, §2(a), Nov. 1, 1988, 102 Stat. 2951.)

§ 6992b. Tracking of medical waste

(a) Demonstration program

Not later than 6 months after November 1, 1988, the Administrator shall promulgate regula-

¹ So in original. Probably should be "exudates".

tions establishing a program for the tracking of the medical waste listed in section 6992a of this title which is generated in a State subject to the demonstration program. The program shall (1) provide for tracking of the transportation of the waste from the generator to the disposal facility, except that waste that is incinerated need not be tracked after incineration, (2) include a system for providing the generator of the waste with assurance that the waste is received by the disposal facility, (3) use a uniform form for tracking in each of the demonstration States, and (4) include the following requirements:

- (A) A requirement for segregation of the waste at the point of generation where practicable.
- (B) A requirement for placement of the waste in containers that will protect waste handlers and the public from exposure.
- (C) A requirement for appropriate labeling of containers of the waste.

(b) Small quantities

In the program under subsection (a), the Administrator may establish an exemption for generators of small quantities of medical waste listed under section 6992a of this title, except that the Administrator may not exempt from the program any person who, or facility that, generates 50 pounds or more of such waste in any calendar month.

(c) On-site incinerators

Concurrently with the promulgation of regulations under subsection (a), the Administrator shall promulgate a recordkeeping and reporting requirement for any generator in a demonstration State of medical waste listed in section 6992a of this title that (1) incinerates medical waste listed in section 6992a of this title on site and (2) does not track such waste under the regulations promulgated under subsection (a). Such requirement shall require the generator to report to the Administrator on the volume and types of medical waste listed in section 6992a of this title that the generator incinerated on site during the 6 months following the effective date of the requirements of this subsection.

(d) Type of medical waste and types of generators

For each of the requirements of this section, the regulations may vary for different types of medical waste and for different types of medical waste generators.

(Pub. L. 89–272, title II, \$11003, as added Pub. L. 100-582, \$2(a), Nov. 1, 1988, 102 Stat. 2952.)

§ 6992c. Inspections

(a) Requirements for access

For purposes of developing or assisting in the development of any regulation or report under this subchapter or enforcing any provision of this subchapter, any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled medical waste shall, upon request of any officer, employee, or representative of the Environmental Protection Agency duly designated by the Administrator, furnish information relating to such waste, including any tracking forms required to be main-

tained under section 6992b of this title, conduct monitoring or testing, and permit such person at all reasonable times to have access to, and to copy, all records relating to such waste. For such purposes, such officers, employees, or representatives are authorized to—

- (1) enter at reasonable times any establishment or other place where medical wastes are or have been generated, stored, treated, disposed of, or transported from:
 - (2) conduct monitoring or testing; and
- (3) inspect and obtain samples from any person of any such wastes and samples of any containers or labeling for such wastes.

(b) Procedures

Each inspection under this section shall be commenced and completed with reasonable promptness. If the officer, employee, or representative obtains any samples, prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the sample obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained if giving such an equal portion is feasible. If any analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge of the premises concerned.

(c) Availability to public

The provisions of section 6927(b) of this title shall apply to records, reports, and information obtained under this section in the same manner and to the same extent as such provisions apply to records, reports, and information obtained under section 6927 of this title.

(Pub. L. 89–272, title II, §11004, as added Pub. L. 100–582, §2(a), Nov. 1, 1988, 102 Stat. 2952.)

§ 6992d. Enforcement

(a) Compliance orders

(1) Violations

Whenever on the basis of any information the Administrator determines that any person has violated, or is in violation of, any requirement or prohibition in effect under this subchapter (including any requirement or prohibition in effect under regulations under this subchapter) (A) the Administrator may issue an order (i) assessing a civil penalty for any past or current violation, (ii) requiring compliance immediately or within a specified time period, or (iii) both, or (B) the Administrator may commence a civil action in the United States district court in the district in which the violation occurred for appropriate relief, including a temporary or permanent injunction. Any order issued pursuant to this subsection shall state with reasonable specificity the nature of the violation.

(2) Orders assessing penalties

Any penalty assessed in an order under this subsection shall not exceed \$25,000 per day of noncompliance for each violation of a requirement or prohibition in effect under this subchapter. In assessing such a penalty, the Administrator shall take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements.