

112TH CONGRESS
1ST SESSION

H. R. 2546

To amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of medical waste.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2011

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of medical waste.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Waste Man-
5 agement Act of 2011”.

6 **SEC. 2. TRACKING AND DISPOSAL OF MEDICAL WASTE.**

7 (a) DEFINITION OF MEDICAL WASTE.—Section 1004
8 of the Solid Waste Disposal Act (42 U.S.C. 6903) is

1 amended by striking paragraph (40) and inserting the fol-
2 lowing:

3 “(40)(A) Except as provided in subparagraph
4 (C), the term ‘medical waste’ means any solid waste
5 which is generated in the diagnosis, treatment, or
6 immunization of human beings or animals, in re-
7 search pertaining thereto, or in the production or
8 testing of biologicals.

9 “(B) Such term includes the following types of
10 solid waste:

11 “(i) Cultures and stocks of infectious
12 agents and associated biologicals, including cul-
13 tures from medical and pathological labora-
14 tories, cultures and stocks of infectious agents
15 from research and industrial laboratories,
16 wastes from the production of biologicals, dis-
17 carded live and attenuated vaccines, and culture
18 dishes and devices used to transfer, inoculate,
19 and mix cultures.

20 “(ii) Pathological waste, including tissues,
21 organs, and body parts that are removed during
22 surgery or autopsy.

23 “(iii) Waste human blood and products of
24 blood, including serum, plasma, and other blood
25 components.

1 “(iv) Sharps (as such term is defined by
2 the Secretary) that have been used in patient
3 care or in medical, research, or industrial lab-
4 oratories, including hypodermic needles, sy-
5 ringes, pasteur pipettes, broken glass, and scal-
6 pel blades.

7 “(v) Contaminated carcasses, body parts,
8 and bedding of animals that have been exposed
9 to infectious agents during research, production
10 of biologicals, or testing of pharmaceuticals.

11 “(vi) Waste from surgery or autopsy that
12 has been in contact with infectious agents, in-
13 cluding soiled dressings, sponges, drapes, lavage
14 tubes, drainage sets, underpads, and surgical
15 gloves.

16 “(vii) Laboratory waste from medical,
17 pathological, pharmaceutical, or other research,
18 commercial, or industrial laboratories that has
19 been in contact with infectious agents, including
20 slides and cover slips, disposable gloves, labora-
21 tory coats, and aprons.

22 “(viii) Dialysis waste that has been in con-
23 tact with the blood of patients undergoing
24 hemodialysis, including contaminated disposable
25 equipment and supplies such as tubing, filters,

1 disposable sheets, towels, gloves, aprons, and
2 laboratory coats.

3 “(ix) Discarded medical equipment and
4 parts that have been in contact with infectious
5 agents.

6 “(x) Solid waste that is likely to be con-
7 taminated with infectious agents because the
8 wastes have been in contact with humans or
9 animals that are quarantined to protect other
10 humans or animals from communicable disease.

11 “(xi) Solid waste generated during—

12 “(I) the diagnosis or treatment of dis-
13 ease in human beings or animals;

14 “(II) the provision of medical services
15 (including immunizations) to human beings
16 or animals;

17 “(III) post-mortem clean-up or au-
18 topsy preparations for human beings or
19 animals;

20 “(IV) medical research on human
21 beings or animals;

22 “(V) the operation of a syringe ex-
23 change program; or

24 “(VI) the production or testing of a
25 biological product (as defined in section

1 351 of the Public Health Service Act (42
2 U.S.C. 262)).

3 “(C) Such term does not include any hazardous
4 waste identified or listed under subtitle C or any
5 household waste as defined in regulations under sub-
6 title C.

7 “(D) Not later than the last day of the two-
8 year period beginning on the date of enactment of
9 the Medical Waste Management Act of 2011, the
10 Administrator shall promulgate regulations listing
11 types of medical waste.”.

12 (b) AMENDMENT OF SOLID WASTE DISPOSAL ACT.—
13 The Solid Waste Disposal Act is amended by striking sub-
14 title J (42 U.S.C. 6992 et seq.) and inserting the fol-
15 lowing:

16 **“Subtitle J—Medical Waste**
17 **Management Program**

18 **“SEC. 11001. MEDICAL WASTE MANAGEMENT PROGRAM.**

19 “(a) IN GENERAL.—The Administrator shall conduct
20 a medical waste management program for the purpose of
21 protecting human health and the environment from med-
22 ical waste.

23 “(b) COMPONENTS OF PROGRAM.—The program
24 under subsection (a) shall provide for the following:

1 “(1) Tracking medical waste from any gener-
2 ator of such waste to any disposal facility that dis-
3 poses of such waste, including a recordkeeping sys-
4 tem for generators who dispose of medical waste at
5 the same facility where the waste is generated.

6 “(2) A uniform manifest form prepared by the
7 generator of any medical waste that accompanies the
8 waste as it is being transported from a generator to
9 a disposal facility.

10 “(3) Labeling and packaging requirements
11 that—

12 “(A) foster safe handling of the waste;

13 “(B) protect the public from exposure to
14 infectious disease; and

15 “(C) provide for the identification of the
16 generator of the waste.

17 “(4) Storage requirements, including a require-
18 ment for segregation of the waste at the point of
19 generation and during transportation.

20 “(5) Proper disposal of medical waste through
21 appropriate methods of disposal that—

22 “(A) are approved by the Administrator;
23 and

24 “(B) provide adequate protection for the
25 environment and human health.

1 “(6) Monitoring of generators and transporters
2 of medical waste and storage and disposal facilities
3 that store or dispose of medical waste for compliance
4 with the program under this section.

5 “(7) A requirement that such generators, trans-
6 porters, and facilities provide adequate training to
7 individuals who handle medical waste to ensure com-
8 pliance with the program under this section.

9 “(8) A national plan for managing medical
10 waste generated in States with a shortage of dis-
11 posal facilities.

12 “(c) EXEMPTIONS.—

13 “(1) PROPERLY TREATED WASTE.—

14 “(A) IN GENERAL.—Subject to paragraph
15 (4), the Administrator may make an exemption
16 from some or all of the requirements of the pro-
17 gram under subsection (a) for medical waste
18 treated in a method described under subpara-
19 graph (B).

20 “(B) METHODS OF TREATMENT.—For
21 purposes of this paragraph, the Administrator
22 shall promulgate regulations establishing min-
23 imum standards for methods of treating med-
24 ical waste that significantly reduce the potential

1 harm of such waste to the environment and to
2 human health.

3 “(2) STORAGE REQUIREMENTS.—Subject to
4 paragraph (4), the Administrator may make an ex-
5 emption to the requirement under subsection (b)(4)
6 that medical waste be segregated from other waste
7 upon receipt of a petition for such an exemption
8 from a generator, transporter, or storage or disposal
9 facility.

10 “(3) INDIVIDUALS.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (B) and paragraph (4), the Adminis-
13 trator shall make an exemption from the pro-
14 gram under subsection (a) for individuals who
15 generate medical waste through personal use of
16 medical or non-medical products outside of a
17 medical facility.

18 “(B) NO EXEMPTION FOR LARGE VOLUMES
19 OF WASTE.—The Administrator may not make
20 an exemption under subparagraph (A) for an
21 individual who generates 50 pounds or more of
22 medical waste in any calendar month.

23 “(4) PROTECTION OF THE ENVIRONMENT AND
24 HUMAN HEALTH.—The Administrator may not make
25 an exemption under this subsection unless the ex-

1 emption does not endanger the environment or
2 human health, as determined by the Administrator.

3 “(d) REGULATIONS.—

4 “(1) IN GENERAL.—For purposes of the pro-
5 gram under this section, not later than the last day
6 of the one-year period beginning on the date of en-
7 actment of the Medical Waste Management Act of
8 2011, the Administrator shall promulgate regula-
9 tions on tracking, labeling, packaging, storing, han-
10 dling, monitoring, and disposing of medical waste.

11 “(2) VARIATION IN RULES.—The regulations
12 under paragraph (1) may include different rules for
13 different types of medical waste and for different
14 types of medical waste generators.

15 **“SEC. 11002. SPECIFIC REQUIREMENTS FOR GENERATORS,**
16 **TRANSPORTERS, AND STORAGE AND DIS-**
17 **POSAL FACILITIES.**

18 “(a) SPECIFIC REQUIREMENTS FOR GENERATORS.—

19 “(1) IN GENERAL.—A generator of medical
20 waste shall—

21 “(A) provide any transporter that is trans-
22 porting medical waste from the generator to a
23 disposal facility—

24 “(i) with a written assurance that the
25 generator has complied with all labeling,

1 packaging, and storage requirements under
2 section 11001 with respect to such medical
3 waste; and

4 “(ii) with a properly completed mani-
5 fest form for transporting such waste
6 under section 11001(b)(2);

7 “(B) register with the Administrator; and

8 “(C) provide the Administrator with the
9 name of all transporters used by the generator
10 to transport medical waste.

11 “(2) APPLICATION TO TATTOO AND BODY ART
12 ESTABLISHMENTS.—A body art establishment (in-
13 cluding a tattoo parlor) shall be considered to be a
14 generator of medical waste for purposes of this sub-
15 title.

16 “(b) SPECIFIC REQUIREMENTS FOR TRANS-
17 PORTERS.—A transporter of medical waste shall—

18 “(1) not accept medical waste from a generator
19 without receiving a written assurance, with regard to
20 such waste, that is described in subsection (a)(1)(A);

21 “(2) register with the Administrator; and

22 “(3) disclose to the Administrator the number
23 and type of vehicles used by the transporter to
24 transport medical waste and the equipment and

1 methods used to ensure segregation and handling of
2 such waste in accordance with this subtitle.

3 “(c) SPECIFIC REQUIREMENTS FOR STORAGE FA-
4 CILITIES.—An owner or operator of a storage facility
5 shall—

6 “(1) provide notice of the storage of medical
7 waste to the generator of that medical waste; and

8 “(2) register with the Administrator.

9 “(d) SPECIFIC REQUIREMENTS FOR DISPOSAL FA-
10 CILITIES.—An owner or operator of a disposal facility
11 shall—

12 “(1) provide notice of the disposal of medical
13 waste to the generator of that medical waste; and

14 “(2) register with the Administrator.

15 “(e) REGISTRATION.—The Administrator may set
16 appropriate requirements for registration under this sec-
17 tion and may collect reasonable registration fees from gen-
18 erators, transporters, and disposal facilities.

19 “(f) AVAILABILITY OF FEES.—Subject to appropria-
20 tions, fees collected under this section shall remain avail-
21 able for use by the Administrator for purposes of the med-
22 ical waste management program under this subtitle.

23 **“SEC. 11003. INSPECTIONS.**

24 “(a) REQUIREMENTS FOR ACCESS.—

1 “(1) IN GENERAL.—Upon request of any offi-
2 cer, employee, or representative of the Environ-
3 mental Protection Agency duly designated by the
4 Administrator, for purposes of developing or assist-
5 ing in the development of any regulation or report
6 under this subtitle or enforcing any provision of this
7 subtitle, any person who generates, stores, treats,
8 transports, disposes of, or otherwise handles medical
9 waste shall furnish information relating to such
10 waste (including any manifest forms required under
11 section 11001), conduct monitoring or testing, and
12 permit such officer, employee, or representative at
13 all reasonable times to have access to, and to copy,
14 all records relating to such waste.

15 “(2) SPECIFIC ACTIVITIES AUTHORIZED.—To
16 carry out inspections for purposes of the program
17 under section 11001, officers, employees, or rep-
18 resentatives described under paragraph (1) are au-
19 thorized to—

20 “(A) enter at reasonable times any build-
21 ing, vehicle, equipment, container, or other item
22 or place where medical waste is generated,
23 stored, treated, disposed of, or transported;

24 “(B) conduct monitoring or testing relat-
25 ing to such waste;

1 “(C) inspect any such waste and any con-
2 tainers, labels, and documents relating to such
3 waste; and

4 “(D) obtain from any person—

5 “(i) samples of such waste; and

6 “(ii) samples or copies of such con-
7 tainers, labels, and documents.

8 “(b) PROCEDURES.—

9 “(1) PROMPT INSPECTIONS.—Each inspection
10 under this section shall be commenced and com-
11 pleted with reasonable promptness.

12 “(2) SAMPLES.—

13 “(A) IN GENERAL.—If an officer, em-
14 ployee, or representative described under sub-
15 section (a)(1) obtains any samples under sub-
16 section (a)(2)(D), prior to leaving the site of in-
17 spection the officer, employee, or representative
18 shall give to the owner, operator, or agent in
19 charge a receipt describing each sample ob-
20 tained.

21 “(B) ANALYSIS.—If any analysis is made
22 of such samples, a copy of the results of such
23 analysis shall be furnished promptly to the
24 owner, operator, or agent in charge of the site
25 from which such sample was taken.

1 “(c) AVAILABILITY TO PUBLIC.—The provisions of
2 section 3007(b) of this Act shall apply to records, reports,
3 and information obtained under this section in the same
4 manner and to the same extent as such provisions apply
5 to records, reports, and information obtained under sec-
6 tion 3007.

7 **“SEC. 11004. FEDERAL ENFORCEMENT.**

8 “The provisions of section 3008 (except for sub-
9 section (d)(7) and to the extent such section applies to
10 used oil) shall apply to a violation of this subtitle, with
11 respect to medical waste, in the same manner and to the
12 same extent as such provisions apply to a violation of sub-
13 title C, with respect to hazardous waste except that any
14 reference in section 3008 to—

15 “(1) section 3006 shall be treated as a ref-
16 erence to section 11005;

17 “(2) a permit under this subtitle shall be treat-
18 ed as a reference to registration under section
19 11002; and

20 “(3) authorization to operate under section
21 3005(e) shall be treated as a reference to a registra-
22 tion under section 11002.

1 **“SEC. 11005. AUTHORIZED STATE MEDICAL WASTE PRO-**
2 **GRAMS.**

3 “The provisions of section 3006 (except for sub-
4 sections (g) and (h) and paragraphs (3) and (4) of sub-
5 section (e)) shall, to the extent consistent, apply to this
6 subtitle, with respect to medical waste, in the same man-
7 ner as such provisions apply to subtitle C, with respect
8 to hazardous waste, except that any reference in section
9 3006 to—

10 “(1) the date of enactment of this Act shall be
11 treated as a reference to the date of enactment of
12 the Medical Waste Management Act of 2011;

13 “(2) the date of promulgate of regulations
14 under sections 3002, 3004, and 3005, shall be treat-
15 ed as a reference to the date of promulgation of reg-
16 ulations under section 11001, 11002, and 11003;
17 and

18 “(3) January 31, 1986, shall be treated as a
19 reference to December 31, 2011.

20 **“SEC. 11006. SYRINGE DISPOSAL PROGRAM.**

21 “(a) IN GENERAL.—The Administrator shall estab-
22 lish a program on syringe disposal to—

23 “(1) educate the public about acceptable meth-
24 ods for disposal of used syringes generated by indi-
25 viduals through personal use of such syringes out-

1 side of medical facilities, including through house-
2 hold use; and

3 “(2) provide grants to State and local govern-
4 ments and nonprofit and private entities—

5 “(A) to educate the public about such
6 methods; and

7 “(B) to increase access to such disposal
8 methods.

9 “(b) ACCEPTABLE DISPOSAL METHODS.—For pur-
10 poses of this section, acceptable methods of disposal of
11 used syringes shall be determined by the Administrator
12 and may include community drop-off programs, hazardous
13 waste facilities that accept household waste, mail-back
14 programs, syringe exchange programs, and needle destruc-
15 tion devices.

16 “(c) UNACCEPTABLE DISPOSAL METHODS.—For
17 purposes of this section, disposal—

18 “(1) in household garbage is not an acceptable
19 disposal method unless the syringe has been appro-
20 priately (as determined by the Administrator) steri-
21 lized and destroyed; and

22 “(2) through the sewage system is not an ac-
23 ceptable disposal method.

24 **“SEC. 11007. REPORTS TO CONGRESS.**

25 “(a) ANNUAL REPORT.—

1 “(1) IN GENERAL.—Not later than one year
2 after the date of enactment of the Medical Waste
3 Management Act of 2011 and annually thereafter,
4 the Administrator shall report to Congress on the
5 following:

6 “(A) The types, number, and size of gen-
7 erators of medical waste in the United States.

8 “(B) The types and amounts of medical
9 waste generated in the United States.

10 “(C) The methods currently used to han-
11 dle, store, transport, treat, and dispose of the
12 medical waste, including the extent to which
13 such waste is disposed of in sewer systems.

14 “(D) The present and potential costs—

15 “(i) to local economies, persons, and
16 the environment from the improper han-
17 dling, storage, transportation, treatment,
18 or disposal of medical waste; and

19 “(ii) to generators, transporters, and
20 storage and disposal facilities from regula-
21 tions establishing requirements related to
22 tracking, handling, storing, transporting,
23 treating, and disposing of medical waste.

24 “(E) Available and potentially available
25 methods for handling, storing, transporting,

1 and disposing of medical waste and their advan-
2 tages and disadvantages.

3 “(F) Available and potentially available
4 methods for treating medical waste, including
5 methods of sterilization, chemical treatment,
6 and grinding.

7 “(G) The advantages and disadvantages of
8 such treatment methods, including the extent to
9 which such methods—

10 “(i) render medical waste noninfec-
11 tious or less infectious;

12 “(ii) make medical waste unrecogniz-
13 able; and

14 “(iii) protect human health and the
15 environment.

16 “(H) Factors impacting the effectiveness
17 of the treatment methods identified in subpara-
18 graph (F), including quality control and quality
19 assurance procedures, maintenance procedures,
20 and operator training.

21 “(I) Available and potentially available
22 methods for the reuse or reduction of the vol-
23 ume of medical waste generated.

24 “(b) STUDY AND REPORT ON INDIVIDUAL GENERA-
25 TORS.—

1 “(1) STUDY.—The Administrator shall conduct
2 a study on—

3 “(A) the type of medical waste (including
4 used syringes) generated by individuals through
5 personal use of medical products outside of
6 medical facilities;

7 “(B) the volume of such waste;

8 “(C) the availability and cost of disposal
9 and treatment of such waste;

10 “(D) the impact on the environment and
11 human health of excluding such waste from the
12 medical waste management program under sec-
13 tion 11001; and

14 “(E) the extent to which individuals are
15 aware of and use available disposal and treat-
16 ment options for such waste.

17 “(2) REPORT.—Not later than the last day of
18 the one-year period beginning on the date of enact-
19 ment of the Medical Waste Management Act of
20 2011, the Administrator shall submit a report to
21 Congress containing—

22 “(A) the results of the study under para-
23 graph (1);

1 “(B) recommended standards for the han-
2 dling, storage, treatment, and disposal of such
3 waste; and

4 “(C) recommendations for educating the
5 public about such standards.

6 “(c) CONSULTATION.—In preparing the reports
7 under this section, the Administrator shall consult with
8 appropriate State and local agencies.

9 **“SEC. 11008. GENERAL PROVISIONS.**

10 “(a) CONSULTATION.—(1) In promulgating regula-
11 tions under this subtitle, the Administrator shall consult
12 with the States and may consult with other interested par-
13 ties.

14 “(2) The Administrator shall also consult with the
15 International Joint Commission (as established by the
16 Boundary Waters Treaty of 1909 between Canada and the
17 United States) to determine how to track medical waste
18 entering the United States from Canada.

19 “(b) PAPERWORK REDUCTION ACT.—The promulga-
20 tion of such regulations shall not be subject to the Paper-
21 work Reduction Act of 1980.

22 “(c) RELATIONSHIP TO SUBTITLE C.—Nothing in
23 this subtitle shall affect the authority of the Administrator
24 to regulate medical waste under subtitle C of this Act.

1 **“SEC. 11009. EFFECTIVE DATE OF REGULATIONS.**

2 “The regulations promulgated under this subtitle
3 shall take effect on the last day of the 90-day period begin-
4 ning on the date such regulations are promulgated.”.

5 (c) TABLE OF CONTENTS.—The table of contents for
6 the Solid Waste Disposal Act is amended by striking the
7 items relating to subtitle J and inserting the following:

“Subtitle J—Medical Waste Management Program

- “Sec. 11001. Medical waste management program.
- “Sec. 11002. Specific requirements for generators, transporters, and storage
and disposal facilities.
- “Sec. 11003. Inspections.
- “Sec. 11004. Federal Enforcement.
- “Sec. 11005. Authorized State medical waste programs.
- “Sec. 11006. Syringe Disposal Program.
- “Sec. 11007. Reports to Congress.
- “Sec. 11008. General provisions.
- “Sec. 11009. Effective date of regulations.”.

