SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
Second Regular Session)

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SENATE
S. No. 2724

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

AN ACT
REQUIRING THE SECRETARY OF THE DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES TO PROMULGATE REGULATIONS ON THE MANAGEMENT OF MEDICAL WASTE

EXPLANATORY NOTE

The Constitution, Article 2, Sections 15 and 16 provide:

> Section 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.
>
> Section 16. The State shall protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature.

As early as 2003, Republic Act No. 8749, also known as the "Philippine Clean Air Act of 1999," banned the incineration of medical waste. Thus, the proper disposal of infectious medical waste remains a concern among Philippine hospitals that are currently seeking non-incineration ways of treating medical waste.[1]

This bill requires the management of medical wastes. It directs the secretary of the Department of Environment and Natural Resources (DENR) to promulgate regulations on the management of medical waste and to conduct a medical waste management program for the purpose of protecting human health and the environment from medical waste. This program regulates the generation, handling, storage, treatment, and disposal of medical waste.[2]

MIRIAM DEFENSOR SANTIAGO

[1] http://gefmedwaste.org/article.php?id=140.

[2] This bill was originally filed by Rep. Frank Pallone in the U.S. House of Representatives during the 111th Congress.

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Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

AN ACT
REQUIRING THE SECRETARY OF THE DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES TO PROMULGATE REGULATIONS ON THE MANAGEMENT OF MEDICAL WASTE

SECTION 1. *Short Title.* – This Act shall be known as the "Medical Waste Management Act".

SECTION 2. *Tracking and Disposal of Medical Waste.* –

(a) Definition of Medical Waste. – The term "medical waste" means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.

(b) Such term includes the following types of solid waste:

(i) 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.

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

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

(iv) 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.

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

(vi) Waste from surgery or autopsy that has been in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.

(vii) Laboratory waste from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that has been in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.

(viii) Dialysis waste that has been 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.

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

(x) Solid waste that is likely to be contaminated with infectious agents because the wastes have been in contact with humans or animals that are quarantined to protect other humans or animals from communicable disease.

(xi) Solid waste generated during:

(I) the diagnosis or treatment of disease in human beings or animals;

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

(III) post-mortem clean-up or autopsy preparations for human beings or animals;

(IV) medical research on human beings or animals;

(V) the operation of a syringe exchange program; or

(VI) the production or testing of a biological product.

(c) Not later than the last day of the two-year period beginning on the date of effectivity of this Act, the Secretary of the Department of Environment and Natural Resources (here called the "Secretary") shall promulgate regulations listing types of medical waste.

SECTION 3. *Medical Waste Management Program.* –

(a) The Secretary shall conduct a medical waste management program for the purpose of protecting human health and the environment from medical waste.

(b) The program shall provide for the following:

(1) Tracking medical waste from any generator of such waste to any disposal facility that disposes of such waste, including a record keeping system for generators who dispose of medical waste at the same facility where the waste is generated.

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

(3) Labeling and packaging requirements that: foster safe handling of the waste; protect the public from exposure to infectious disease; and provide for the identification of the generator of the waste.

(4) Storage requirements, including a requirement for segregation of the waste at the point of generation and during transportation.

(5) Proper disposal of medical waste through appropriate methods of disposal that are approved by the Secretary; and provide adequate protection for the environment and human health.

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

(7) A requirement that such generators, transporters, and facilities provide adequate training to individuals who handle medical waste to ensure compliance with the program under this section.

(8) A national plan for managing medical waste generated in States with a shortage of disposal facilities.

(c) Exemptions:

(1) Properly Treated Waste. –

(A) Subject to paragraph (4), the Secretary may make an exemption from some or all of the requirements of the program for medical waste treated in a method described under subparagraph (B).

(B) Methods of Treatment. – For purposes of this paragraph, the Secretary shall promulgate regulations establishing minimum standards for methods of treating medical waste that significantly reduce the potential harm of such waste to the environment and to human health.

(2) Storage Requirements. – Subject to paragraph (4), the Secretary may make an exemption to the requirement under subsection (b)(4) that medical waste be segregated from other waste upon receipt of a petition for such an exemption from a generator, transporter, or storage or disposal facility.

(3) Individuals. –

(A) Subject to subparagraph (B) and paragraph (4), the Secretary shall make an exemption from the program under subsection (a) for individuals who generate medical waste through personal use of medical or non-medical products outside of a medical facility.

(B) No Exemption for Large Volumes of Waste. – The Secretary may not make an exemption under subparagraph (A) for an individual who generates 50 pounds or more of medical waste in any calendar month.

(4) Protection of the Environment and Human Health. – The Secretary may not make an exemption under this subsection unless the exemption does not endanger the environment or human health, as determined by the Secretary.

(d) Regulations. –

(1) For purposes of the program, not later than the last day of the one-year period beginning on the date of effectivity of this Act, the Secretary shall promulgate regulations on tracking, labeling, packaging, storing, handling, monitoring, and disposing of medical waste.

(2) Variation in Rules. – The regulations under paragraph (1) may include different rules for different types of medical waste and for different types of medical waste generators.

SECTION 4. *Specific Requirements for Generators, Transporters, and Storage and Disposal Facilities.* –

(a) Specific Requirements for Generators. –

(1) A generator of medical waste shall:

(A) provide any transporter that is transporting medical waste from the generator to a disposal facility –

(i) with a written assurance that the generator has complied with all labeling, packaging, and storage requirements under section 3 with respect to such medical waste; and

(ii) with a properly completed manifest form for transporting such waste under section 3 (b)(2);

(B) register with the Secretary; and

(C) provide the Secretary with the name of all transporters used by the generator to transport medical waste.

(2) Application to Tattoo and Body Art Establishments. – A body art establishment (including a tattoo parlor) shall be considered to be a generator of medical waste for purposes of this subtitle.

(b) Specific Requirements for Transporters. – A transporter of medical waste shall:

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

(2) register with the Secretary; and

(3) disclose to the Secretary the number and type of vehicles used by the transporter to transport medical waste and the equipment and methods used to ensure segregation and handling of such waste in accordance with this Act.

(c) Specific Requirements for Storage Facilities. – An owner or operator of a storage facility shall provide notice of the storage of medical waste to the generator of that medical waste; and register with the Secretary.

(d) Specific Requirements for Disposal Facilities. – An owner or operator of a disposal facility shall provide notice of the disposal of medical waste to the generator of that medical waste; and register with the Secretary.

(e) Registration. – The Secretary may set appropriate requirements for registration under this section and may collect reasonable registration fees from generators, transporters, and disposal facilities.

(f) Availability of Fees. – Subject to appropriations, fees collected under this section shall remain available for use by the Secretary for purposes of the medical waste management program under this subtitle.

SECTION 5. *Inspections*. –

(a) Requirements for Access. –

(1) Upon request of any officer or employee or representative of the Secretary for purposes of developing or assisting in the development of any regulation or report under this Act or enforcing any of its provision, any person who generates, stores, treats, transports, disposes of, or otherwise handles medical waste shall furnish information relating to such waste (including any manifest forms required under section 3), conduct monitoring or testing, and permit such officer, employee, or representative at all reasonable times to have access to, and to copy, all records relating to such waste.

(2) Specific Activities Authorized. – To carry out inspections for purposes of the program under section 3, officers, employees, or representatives described under paragraph (1) are authorized to:

(A) enter at reasonable times any building, vehicle, equipment, container, or other item or place where medical waste is generated, stored, treated, disposed of, or transported;

(B) conduct monitoring or testing relating to such waste;

(C) inspect any such waste and any containers, labels, and documents relating to such waste; and

(D) obtain from any person samples of such waste; and samples or copies of such containers, labels, and documents.

(b) Procedures. –

(1) Prompt Inspections. – Each inspection under this section shall be commenced and completed with reasonable promptness.

(2) Samples. –

(A) If an officer, employee, or representative described under subsection (a)(1) obtains any samples under subsection (a)(2)(D), prior to leaving the site of inspection the officer, employee, or representative shall give to the owner, operator, or agent in charge a receipt describing each sample obtained.

(B) 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 site from which such sample was taken.

SECTION 6. *Syringe Disposal Program.* –

(a) The Secretary shall establish a program on syringe disposal to:

(1) educate the public about acceptable methods for disposal of used syringes generated by individuals through personal use of such syringes outside of medical facilities, including through household use; and

(2) provide grants to State and local governments and nonprofit and private entities:

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

(B) to increase access to such disposal methods.

(b) Acceptable Disposal Methods. – For purposes of this section, acceptable methods of disposal of used syringes shall be determined by the Secretary and may

include community drop-off programs, hazardous waste facilities that accept household waste, mail-back programs, syringe exchange programs, and needle destruction devices.

(c) Unacceptable Disposal Methods. – For purposes of this section, disposal:

(1) in household garbage is not an acceptable disposal method unless the syringe has been appropriately (as determined by the Secretary) sterilized and destroyed; and

(2) through the sewage system is not an acceptable disposal method.

SECTION 7. *Reports to Congress.* –

(a) Annual Report –

(1) Not later than one year after the date of effectivity of this Act and annually thereafter, the Secretary shall report to Congress on the following:

(A) The types, number, and size of generators of medical waste in the country.

(B) The types and amounts of medical waste generated in the country.

(C) The methods currently used to handle, store, transport, treat, and dispose of the medical waste, including the extent to which such waste is disposed of in sewer systems.

(D) The present and potential costs:

(i) to local economies, persons, and the environment from the improper handling, storage, transportation, treatment, or disposal of medical waste; and

(ii) to generators, transporters, and storage and disposal facilities from regulations establishing requirements related to tracking, handling, storing, transporting, treating, and disposing of medical waste.

(E) Available and potentially available methods for handling, storing, transporting, and disposing of medical waste and their advantages and disadvantages.

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

(G) The advantages and disadvantages of such treatment methods, including the extent to which such methods:

(i) render medical waste noninfectious or less infectious;

(ii) make medical waste unrecognizable; and

(iii) protect human health and the environment.

(H) Factors impacting the effectiveness of the treatment methods identified in subparagraph (F), including quality control and quality assurance procedures, maintenance procedures, and operator training.

(I) Available and potentially available methods for the reuse or reduction of the volume of medical waste generated.

(b) Study and Report on Individual Generators. –

(1) Study. – The Secretary shall conduct a study on:

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

(B) the volume of such waste;

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

(D) the impact on the environment and human health of excluding such waste from the medical waste management program under section 3; and

(E) the extent to which individuals are aware of and use available disposal and treatment options for such waste.

(2) Report. – Not later than the last day of the one-year period beginning on the date of effectivity of this Act, the Secretary shall submit a report to Congress containing:

(A) the results of the study under paragraph (1);

(B) recommended standards for the handling, storage, treatment, and disposal of such waste; and

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

(c) Consultation. – In preparing the reports under this section, the Secretary shall consult with appropriate State and local agencies.

SECTION 8. *Separability Clause.* – If any provision of this Act shall be declared unconstitutional, any other provision not affected thereby shall remain in full force and effect.

SECTION 9. *Repealing Clause.* – All laws, decrees, orders, rules and regulations, or parts thereof inconsistent with this Act are hereby repealed or amended accordingly.

SECTION 10. *Effectivity.* – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,

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