(S. B. 1393)

(No. 180)

(Approved August 6, 2008)

AN ACT

To establish the public policy of the Commonwealth of Puerto Rico regarding the generation, management, transportation, and disposal of biomedical waste; establish the provisions that must be approved by the Environmental Quality Board for implementing the Management Program; establish the method for treating biomedical waste; establish penalties; and for other purposes.

STATEMENT OF MOTIVES

During the 1980s, the United States press broadcasted through television some images of the beaches of New Jersey that frightened the United States Congress. These images evidenced that the beaches of New Jersey had become deposits of hypodermic needles, blood plasma bags, and containers labeled with names of medical substances, among other things. The diffusion of these images served to raise awareness as to the risks and hazards that the improper disposal of biomedical waste could pose to the health and the environment. In light of these events, the United States Congress approved the Medical Waste Tracking Act in 1988.

In general terms, the Medical Waste Tracking Act established mechanisms whereby manifests are used to track biomedical waste from the time it originates to its final disposal. Furthermore, this legislation established a two-year demonstration program during which the United States Environmental Protection Agency (EPA) gathered information from participating States, in order to submit reports to Congress on the success of

the Law and recommendations on how to draft legislation on biomedical and pathological waste. The Commonwealth of Puerto Rico, through the Environmental Quality Board, was included in said Program, and in 1989, it formally began its activities to enforce the same.

On November 10, 1997, the Environmental Quality Board promulgated Regulation No. 5717, for the purpose of regulating the management and operations of non-hazardous waste disposal facilities. Within said group of waste are biomedical waste, used oil, tires and compost.

For the past four years, Puerto Rico has generated approximately 75 million pounds of biomedical waste. In 2003 alone, Puerto Rico generated approximately 20 million pounds. Most of such biomedical waste is generated on a daily basis in hospitals and clinical laboratories. However, veterinarians, odontologists, blood banks, long-term care centers, funeral homes, and universities also generate this kind of waste.

In spite of the importance of the proper disposal of biomedical waste to our environment, the code of laws of Puerto Rico does not have a statute that establishes the minimal parameters that must be met by entities generating, managing, transporting or disposing of biomedical waste.

Contrary to biomedical waste, other non-hazardous solid waste has been regulated through legislation. In the case of tires, this Legislature approved Act No. 171 of August 31, 1996, known as the “Tire Management Act,” to establish, among other things, the public policy on the use, handling, and disposal of tires. With respect to used oil, this Legislature approved Act No. 172 of August 31, 1996, known as the “Act for the Proper Management of Used Oil in Puerto Rico,” to establish, among other things,

the public policy on the collection, recovery, proper management, and disposal of used oil. It is therefore necessary —within non-hazardous waste disposal field—for this Legislature to set forth the public policy on the management of biomedical waste in Puerto Rico.

Aware of the provisions of Section 9 of Act No. 416 of September 22, 2004, known as the "Environmental Public Policy Act," this Legislature empowered the Environmental Quality Board to adopt, promulgate, amend, and repeal rules and regulations on the disposal of solid waste and to establish sites and methods for the disposal thereof. However, of all non-hazardous solid waste, we understand that biomedical waste requires a separate and special legislation.

Through this legislation, the Environmental Quality Board is empowered to implement a biomedical waste management program through the promulgation of a resolution; it is also designated as the agency responsible for the enforcement of the provisions of this Act. At present, the Environmental Quality Board has the technical personnel with specialized knowledge to manage all that pertains to the handling and disposal of biomedical waste.

This Legislature deems that the improper handling of biomedical waste could entail nefarious consequences to the environment; therefore, it promotes the establishment of a coherent public policy on this issue.

BE IT ENACTED BY THE LEGISLATURE OF PUERTO RICO:

Section 1.—Title.—

This Act shall be known as the "Regulated Biomedical Waste Management Act."

Section 2.— Definitions.—

The following words or phrases shall have the meaning stated below:

a. “Infectious Agent” means microorganisms such as viruses and bacteria that may invade and reproduce in bodily tissues that are capable of causing diseases or adversely affecting human health.

b. “Regulated Biomedical Waste” means waste that has been submitted to a process that guarantees more than eighty percent (80%) of its destruction, and may not be recognizable nor reused after being ruined, mutilated, destructed, broken into pieces, melted, compacted, thermally destructed, encapsulated, compacted or turned into ashes after being incinerated in such a way that it cannot be reused in the event of inadequate management. These may be any of the following:

(1) Cultures, Stocks and Associated Biologicals:

(A) Cultures, stocks of infectious agents and biological products;

(B) Live or attenuated vaccines;

(C) Culture dishes and devices used to transfer, inoculate or mix cultures that have been used.

(2) Pathological Waste:

(A) Human pathological waste that has been removed through any procedure;

(B) Specimens of body fluids and their containers;

(C) Fluids associated with embalming;

(D) Animal carcasses.

(3) Human Blood and Blood Byproducts:

(A) Discarded human blood in its liquid state;

(B) Blood byproducts;

(C) Materials saturated with blood or blood byproducts or that were saturated with such substances and still have traces thereof when dry.

(4) Sharp Waste:

Sharp or piercing objects and glass objects of the kind used in the treatment of humans or animals, medical research or industrial laboratories, whether used or not, due to the physical harm these may cause to human beings, such as puncture wounds or lacerations.

(5) Animal Waste:

Carcasses or body parts of animals suspected to be contaminated with transmissible diseases or exposed to infectious agents. This also includes those places were these animals are kept to sleep.

(6) Isolation Waste:

Biological waste and waste materials contaminated with human and animal blood, excretions, secretions, and exudations, which have been isolated to protect others from a possible transmission of contagious diseases.

(7) Exclusions and exceptions:

The following shall not be considered to be regulated medical waste:

(A) Domestic waste;

(B) Ashes from incinerators of regulated medical waste;

(C) Corpses, human parts and remains to be buried in cemeteries;

(D) Carcasses, animal parts and remains to be buried;

(E) Biomedical waste previously regulated that has undergone treatment or any other kind of destruction as provided in this Act;

(F) Etiological agents which are transported within Puerto Rico following the applicable federal and state regulations;

(G) Samples of regulated biomedical waste transported by personnel from the Board;

(H) Biomedical waste that does not contain infectious agents. The person requesting an exemption shall demonstrate to the satisfaction of the Board that such biomedical waste does not contain infectious agents.

(8) Any non-hazardous solid waste which has been affected, affects, is mixed or enters into direct contact with regulated biomedical waste shall become regulated biomedical waste, even when they may be physically separated from one another. In the event that hazardous or radioactive solid waste is being affected, enters into direct contact, affects or is mixed with regulated biomedical waste, the result of such mixture shall be subject to the requirements of law or the most restrictive state and federal regulations.

c. “Destroyed Regulated Biomedical Waste” means waste that has been submitted to a process that guarantees that this kind of waste may not be reused after being ruined, mutilated, broken into pieces, melted, compacted,

destructed, encapsulated, compacted or turned into ashes after being incinerated in such a way that it cannot be reused in the event of inadequate management.

d. “Treated Regulated Biomedical Waste” means the regulated biomedical waste that has been submitted to a decontamination or sterilization process, but that has not been destroyed; hence its physical characteristics have not been changed.

e. “Biomedical Waste Generator” means any natural or juridical person, including, among others, public or private hospitals, public or private forensic or research laboratories, embalming centers, animal treatment and research units, companies, or industrial laboratories engaged in the application of biotechnology for research or production purposes, medical, dental or veterinary offices, who in the practice of their profession, industrial activity or service rendering produce biomedical waste, among others.

f. “Incineration” means the controlled thermal oxidation process of any matter.

“Final Biomedical Waste Disposal Facility” means the facility where incineration, treatment, and destruction of regulated biomedical waste is performed, including such facilities for the destruction or grinding, thermal destruction or encapsulation or compacting, used to destroy regulated biomedical waste that has been previously submitted to a treatment and destruction process, so that the regulated biomedical waste loses its usefulness as such, that is not

infectious and that more than eighty percent (80%) of the destruction thereof is guaranteed, nor that it may be recognizable or neutralized so as to become non-special solid waste, for the tracking process to be completed. Furthermore, this definition shall apply to regulated biomedical waste exporters, and the pre-transport requirements shall not apply.

g. "Board" means the Environmental Quality Board, an agency of the Government of the Commonwealth of Puerto Rico created by virtue of Section 7 of Act No. 416 of September 22, 2004, known as the "Environmental Public Policy Act."

h. "Clinical Laboratory" means any research, analysis or clinical facility that performs analyses relative to health care. This includes, but is not limited to, medical, pathological, and pharmacological research, as well as commercial and industrial laboratories.

i. "Intermediate Regulated Biomedical Waste Manager" means a facility or a person that temporarily stores or processes regulated biomedical waste. This term does not include the final disposal facilities, nor transportation services, however, pre-transport requirements shall apply.

j. "Manifest" means the document approved by the Board which identifies the amount, composition, volume, size, origin, route and destination, as it may apply, of some of the waste that is going to be transported within the jurisdiction

of Puerto Rico to a facility for its management, storage, recycling, reuse, processing, exportation, disposal, incineration, treatment or destruction.

k. "Person" means the juridical entity, natural person or group of private or public entities that is responsible for any activity controlled by this Act. This includes federal and state agencies, municipalities, public and private consortia and corporations, associations, cooperatives, trusts and partnerships.

l. "Biological Products" means the preparations made from live organisms or its products, including vaccines, cultures, and others to be used in the diagnosis, immunization or treatment of humans or animals or in research.

m. "Biomedical Waste Treatment" means any method, technique or process designated to change the biological nature or the composition, without altering the physical features, of any regulated biomedical waste in such a way that its ability to cause diseases is reduced or eliminated, but its identity as such is preserved.

Section 3.- Biomedical Waste Management Program.

The Board shall continue to implement the existing biomedical waste management program, pursuant to the provisions of this Act.

Section 4.- Powers and Responsibilities of the Board.

The Board shall have the following powers and responsibilities:

(a) Amend the pertinent regulations in order to adapt them to the provisions of this Act.

(b) Hold hearings on the issues covered by this Act, and compel the appearance of witnesses and present evidence.

(c) Issue the orders that it may deem necessary to achieve the purposes of this Act, and ensure compliance through administrative or judicial proceedings.

(d) Request, collect and disclose information on the management, treatment, transportation, and disposal of biomedical waste.

Section 5. Regulations

The Board is responsible for keeping the Regulations in effect updated which, in addition to the establishment of the Biomedical Waste Management Program, shall provide for the following:

(a) The responsibilities of the biomedical waste generators in Puerto Rico, as well as of those who import biomedical waste into our jurisdiction. It shall specify the events in which the generator is not bound to use the services of a carrier authorized by the Board and when it is not bound to fill out a manifest. It shall provide for the obligation to have a biomedical waste management plan within the facility, and for the obtainment of the corresponding permits. Lastly, it shall provide for the training program for employees that manage biomedical waste.

(b) The pre-transport responsibilities of the biomedical waste generator or intermediate manager, including the requirements of waste segregation, packaging, labeling, storage, and reuse of containers.

(c) The responsibilities of the carriers, including the obtainment of permits to transport biomedical waste. It shall provide for the conditions to accept biomedical waste for transportation. It shall

also specify the requirements of the vehicles to be used to transport the biomedical waste, the transportation requirements and the responsibilities of the carriers, especially in the event of accidents and spills.

(d) The content and form of the manifest that every generator, carrier, intermediate manager or final disposal facility that stores, separates, collects, transports, treats, recovers or disposes of biomedical waste in Puerto Rico shall have at all times. In the event that it is only necessary to keep a logbook, the Board shall provide for the content of the same. Likewise, this Regulation shall provide for the obligations of the generator, carrier, intermediate manager or final disposal facility, as well as for everything related to the exception reports.

(e) Which documents, regarding the use and management of biomedical waste, shall be kept by a biomedical waste generator, carrier, intermediate manager or final disposal facility.

Section 6.- Biomedical Waste Treatment Methods

It shall be understood as treatment the methods, techniques or processes designed to change the composition or biological features of the waste, without altering the physical features of the waste, so as to eliminate the hazard associated to an infectious agent that may be present in such waste. It shall be understood that this process has been completed when more than eighty percent (80%) of efficiency is guaranteed, in each type of RBW (Regulated Biomedical Waste), when ruined, mutilated or broken into pieces in such a way that these are not recognizable or reusable as regulated biomedical waste.

(a) Except as provided in subsections (b) and (c), a person that generates or treats biomedical waste shall ensure that such biomedical waste has been processed by one of the following methods before disposing of the same:

A. Incineration in a facility authorized for treatment of biomedical waste with air control or some other method of incineration approved by the Board, which provides for the full combustion of the waste until it turns into ashes, whether carbonized or mineralized.

B. A treatment that guarantees that the waste may not be recognizable and reused after being ruined, broken into pieces, mutilated, melted, or compacted and encapsulated after melted, and it is free of infectious agents in such a way that its capacity to cause diseases has been eliminated.

1. The sterilization or disinfection by steam in a facility certified for the treatment of biomedical waste or by other method of sterilization that follows the operating procedures below for steam sterilization or some other type of sterilization:

(A) Written standard operating procedures shall be established for the biological indicators or for other indicators of adequate sterilization, which have been approved by the Board for each steam sterilization facility, including the duration, temperature, pressure, type of waste, container lock, load pattern, water content, and maximum amount to be loaded.

(B) The thermometer indicators and the temperature log shall be verified after each full cycle to ensure that 121° Celsius (250° Fahrenheit) have been reached at least half an hour after, depending on the amount and density of the load, in order to achieve full sterilization of the load. Thermometer calibration shall be annually verified. The records of thermometer calibration verification shall be kept as part of the installation files for a three (3)-year period or that specified by regulations.

(C) The biological indicator *Bacillus stearothermophilus* or other indicator of adequate sterilization as it has been approved by the regulatory agency, shall be placed at the center of the processed load under the standard operating conditions at least once every forty-eight (48) hours, to confirm that the conditions for adequate sterilization have been met.

(D) The records of the procedures specified in subclauses (A), (B), and (C) shall be conserved for a period of not less than three (3) years.

2. Water steam sterilization with a suction system. Through this method, all regulated biomedical waste are submitted to a thermal treatment in the autoclave systems, and are melted and encapsulated during the sterilization process, which renders them into a final unrecognizable plastic mass product that when exposed to the environment temperature hardens permanently, preventing the waste to be potentially

reused. In such cases, the material thus treated shall be deemed to be destroyed for all corresponding legal purposes, insofar as the same shall not be reusable.

(A) Other alternative methods to treat biomedical waste are:

(i) The ones approved by the Board.

(ii) The ones resulting in the destruction of pathogens.

(B) Any other alternative method for the disposal of biomedical waste shall be evaluated by the Board and approved or rejected pursuant to the criteria established by this Section.

(b) Medical waste may be disposed of through the public sewer system without being treated, if it is not waste that poses a biological risk, as defined, which is in a liquid or semi-liquid state, and its disposal is consistent with the requirements for waste disposal through the public sewer system imposed by the Aqueduct and Sewer Authority.

(1) Medical waste that poses biological risks may be treated through chemical disinfection, if the medical waste is in a liquid or semi-liquid state, and the chemical disinfection method used is recognized, as well as if the use of chemical disinfection as a treatment method has been identified in the plan for the management of biomedical waste of such a facility.

(2) If the waste is not treated through chemical disinfection pursuant to clause (1), the waste may be treated through one of the methods specified in subsection (a).

(3) Upon chemical disinfection treatment, the medical waste may be disposed of through the public sewer system, if its disposal is consistent with the requirements for waste disposal through the public sewer system as established by the Aqueduct and Sewer Authority, and such disposal is in compliance with the requirements imposed by the owner or operators of the public sewer system.

(c) Recognizable body parts shall be disposed, with the exception of teeth that are not considered infectious by the physician and surgeon or dentist who handled the case, through their burial or pursuant to subsection (a) of this Section, unless they pose a risk, in which case they should be sterilized or disinfected in such a way that prior to their disposal they be rendered free of infectious diseases. This provision shall not apply to carcasses.

(d) Sharp waste shall become non-infectious prior to its disposal through one of the following methods:

(1) Incineration.

(2) Steam sterilization.

(3) Destruction, mutilation, breakage into pieces, encapsulation or compaction after it has been melted.

(4) Disinfection though alternative methods approved by he Board.

(5) Sharp objects turned into non-infectious pursuant to this Section may be disposed of as if they were non-hazardous solid waste, if these are not hazardous for any other cause.

(6) Treatment of sharp waste, in compliance with clauses (2) and (3), within the facilities for treatment of biomedical waste in the structure shall ensure that, prior to the disposal of treated sharp waste, these have been destroyed or the access of the public to such sharp waste has been hindered.

(e) Each authorized facility for the treatment of biomedical waste shall provide the Board with an emergency action plan, which shall be followed by the facility in order to ensure the adequate disposal of medical waste in the event of equipment breakdown, a natural disaster or other circumstances.

(f) Carcasses shall be treated pursuant to the provisions of this Section, when the cause of death of the animal was an infectious disease, if according to the opinion of the veterinarian or the local health official who treated the animal, the carcass poses a risk of infection to human beings, in which case it shall be treated prior to its disposal as non-hazardous solid waste.

Section 7.- Orders

(a) When the Board has sufficient evidence to conclude that the provisions of this Act or its Regulations have been violated or are being violated, it may:

(1) Issue an order:

(A) Imposing an administrative fine for each violation; or

(B) Requiring immediate compliance with this Act or with its Regulations; or

(C) Both; or

(2) Appear before the Court of First Instance with competence to seek the corresponding recourse, including a permanent or preliminary or provisional injunction. Any judgment pronounced pursuant to the provisions of this Act shall specifically indicate the nature of the violation(s) incurred.

(b) Notwithstanding the provisions of clause (1) of this Section, if the Board understands that there is a specific condition of contamination or that a generator, storage deposit, carrier or provider of treatment and final disposal of hazardous biological waste poses an imminent danger to public health or to the environment's safety, it may issue an order to immediately discontinue the generation of such waste. With this order, the Board shall notify all persons concerned of the holding of a hearing, which shall be conducted not later than forty-eight (48) hours following the issue of the order. Immediately after the hearing is held, the Board shall confirm, modify or render ineffective the order so issued.

(c) When the Board issues an order that includes an administrative fine, pursuant to the provisions of subsection (a) of this Section, such fine may not be greater than twenty-five thousand (25,000) dollars for each violation.

(d) When the Board issues an order to require compliance with the provisions of this Act or of its Regulations, within the term specified in the order, and if the violator does not take corrective measures within the specified period, the Board may impose an administrative fine that may not exceed the amount of twenty-five thousand (25,000) dollars for each day extended beyond the period established in such order.

(e) The Board shall charge for services rendered or the personnel used as a consequence of the violation of the norms and regulations related to this Act, regardless of the administrative fine provided in subsection (d) of this Act.

Section 8.- Public Hearings

(a) Any person affected by a Board's order may request the holding of a hearing within fifteen (15) days following the notice of the order. Such a hearing shall be held during the thirty (30) days following the receipt of the request.

(b) The Board may hold a hearing for the alleged violator of any of the provisions of this Act or of its Regulations to appear before the Board so he/she may answer to the charged violations. Such a hearing shall be held at any time before the order issued becomes effective.

(c) Upon the holding of a hearing, pursuant to the provisions of subsections (a) and (b) of this Section, the Board shall confirm, modify or render ineffective the previously issued order.

(d) None of the provisions of this Section shall be deemed applicable to the specific case detailed in subsection (b) of Section 7 of this Act.

Section 9.- Judicial Review

Any person who is adversely affected by a determination of the Board, pursuant to the provisions of this Act, may request reconsideration within a term of twenty (20) days starting as of the date the notice of the determination was filed in the records. Such a request for reconsideration shall be made in writing and shall explain the grounds for the same.

The Environmental Quality Board shall review the request within the first fifteen (15) days after it was presented. If the request was rejected outright or if no action was taken within fifteen (15) days, the term of thirty (30) days to request judicial review shall start to count again as of the notice of such rejection or as of the expiration of these fifteen (15) days, as the case may be. If any determination is to be taken in considering such request, the term to request a review before the Circuit Court of Appeals shall start to count as of the date in which a copy of the notice of resolution was filed in the records.

Section 10.- Penalties

All natural or juridical persons who violate the provisions of this Act or the regulations promulgated thereunder shall incur a felony and, if convicted, shall be punished by imprisonment for a fixed term of three (3) years. In the event of aggravating circumstances, the fixed penalty shall be increased to a maximum of up to five (5) years. In the event of extenuating circumstances, the penalty may be reduced to a minimum of two (2) years. The Court, in its discretion, may impose a fixed imprisonment penalty established or a fine of up to fifty thousand (50,000) dollars for each day of violation, or both punishments.

Section 11.- Severability Clause

The provisions of this Act are independent from one another, and if any of them were to be declared unconstitutional by any Court with competent jurisdiction, the decision of said Court shall not affect nor invalidate any of the remaining provisions, except when the Court's decision expressly states so.

Section 12.- Amendments to the Regulations in Effect

The Board has one hundred-eighty (180) days after the approval of this Act to amend the regulations in effect and to implement the applicable provisions.

Section 13.- Effectiveness

This Act shall take effect immediately after its approval.

CERTIFICATION

I hereby certify to the Secretary of State that the following **Act No. 180 (S. B. 1393)** of the **7th Session of the 15th Legislature** of Puerto Rico:

AN ACT to establish the public policy of the Commonwealth of Puerto Rico regarding the generation, management, transportation, and disposal of biomedical waste; establish the provisions that must be approved by the Environmental Quality Board for implementing the Management Program; establish the method for treating biomedical waste; establish penalties; and for other purposes.

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, today 19th of January of 2010.

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Director