

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1989

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HOUSE BILL 1045*

Short Title: Infectious Waste Control.

(Public)

Sponsors: Representatives Diggs and Loflin.

Referred to: Human Resources.

April 6, 1989

1 A BILL TO BE ENTITLED
2 AN ACT TO REGULATE BIOMEDICAL AND INFECTIOUS WASTE.
3 The General Assembly of North Carolina enacts:
4 Section 1. Article 9 of Chapter 130A is amended by adding a new Part to
5 read:

6 **“PART 4.**
7 **“INFECTIOUS WASTE CONTROL.**
8 **”§ 130A-310.15. Legislative findings; public purpose.**

9 The biomedical community generates waste contaminated with pathogenic
10 organisms capable of transmitting disease to health care and waste management workers
11 who may be exposed to this material. Improperly managed infectious waste poses a
12 potential threat to public health when untreated or when incompletely treated and
13 discarded as general solid waste. Such waste also provides an aesthetic problem and
14 contributes to environmental degradation through improper treatment and disposal
15 technologies.

16 The General Assembly finds that:

- 17 (1) Infectious waste constitutes an environmental, health, and aesthetic
18 problem that is not adequately controlled by existing federal or State
19 regulation.
20 (2) Careful management of the infectious waste stream is necessary and
21 desirable to protect the public and individuals who may be exposed to
22 potential pathogens during their work, and to minimize environmental
23 degradation caused by inadequate treatment or inappropriate disposal
24 methods.

1 It is the purpose of this Part to assure the safe collection, transportation,
2 treatment, and disposal of infectious waste through effective standards and regulations.

3 **"§ 130A-310.16. Definitions.**

4 Unless the context requires otherwise, for the purpose of this Part:

- 5 (1) 'Chemotherapeutic waste' means all materials that have come in
6 contact with, and have no more than trace amounts of, cytotoxic or
7 antineoplastic agents.
- 8 (2) 'Disposal' means the final placement of treated infectious waste in
9 permitted landfills or the permitted sewerage of liquids to a municipal
10 waste water treatment system.
- 11 (3) 'Infectious waste' means:
- 12 a. Sharps, including needles, tubing with needles attached, scalpel
13 blades, glassware, and syringes that have been removed from
14 their original sterile containers.
- 15 b. Pathological waste, including all human tissues and anatomical
16 parts.
- 17 c. Biological waste, including blood and blood products,
18 excretions, exudates, secretions, suctionings, and other body
19 fluids which may not be directly discarded into a municipal
20 sewer system.
- 21 d. Isolation waste, including all waste from the care or treatment
22 of patients isolated to prevent the spread of communicable
23 diseases except reverse (protective) isolation.
- 24 e. Cultures and stocks of microorganisms and associated
25 biologicals, including specimen cultures, waste from production
26 of biologicals and serums, and discarded live or attenuated
27 vaccines.
- 28 f. Laboratory waste which has come in contact with pathogenic
29 organisms, including culture dishes, transfer devices, paper, and
30 cloth.
- 31 g. Surgical waste, including all materials discarded from surgical
32 procedures, disposable gowns, soiled dressings, sponges, casts,
33 lavage tubes, drainage sets, underpads, and surgical gloves.
- 34 h. Chemotherapeutic waste.
- 35 i. Any other waste that the Commission determines may be
36 infectious or harmful due to its biological infectious nature and
37 that requires special handling and disposal.
- 38 (5) 'Pathogenic organism' or 'Pathogens' means microorganisms that can,
39 under certain circumstances, produce disease.
- 40 (6) 'Person' means any individual, partnership, company, corporation,
41 association, firm, organization, or group of individuals, or any officer
42 or employee thereof.
- 43 (7) 'Sharps' means any discarded article that may cause puncture or cuts.

- 1 (8) 'Storage' means the containment of infectious waste in a manner that is
2 not treatment or disposal.
- 3 (9) 'Transport' means the movement of infectious waste from the point of
4 generation to any intermediate points and finally to the point of
5 treatment or disposal.
- 6 (10) 'Treatment' means any method, technique, or process designed to
7 change the character or composition of any infectious waste so as to
8 neutralize the waste or render it noninfectious.

9 **"§ 130A-310.17. Scope of this Part.**

10 Provisions and requirements of this Part apply to infectious waste generated,
11 transported, or disposed of within the State regardless of place of origin. Provisions and
12 requirements of this Part apply to chemotherapeutic waste only if the waste is to be
13 incinerated.

14 All persons who generate infectious waste, except individuals who generate
15 infectious waste from a single-family residence or dwelling during self-treatment, are
16 subject to the provisions of this Part. Self-treatment includes administration of health
17 care by the patient, family member, or other individual not associated with a home
18 health care service or organization.

19 **"§ 130A-310.18. Infectious waste manifests.**

20 The Commission and the Department shall develop and implement a manifest-
21 based tracking system designed to assure that infectious waste is properly managed and
22 treated prior to disposal.

23 **"§ 130A-310.19. Duties of infectious waste generators.**

24 (a) Each infectious waste generator shall register with the Agency, on forms
25 provided by the Department, to notify the Commission of his intent to generate
26 infectious waste.

27 (b) All infectious wastes shall be separated at the point of generation and
28 managed as a separate waste stream. Infectious waste shall be isolated and contained
29 from the time of generation until treatment.

30 (c) Infectious waste shall not be compacted, ground, or otherwise physically
31 altered prior to treatment.

32 (d) Waste generators should implement waste reduction and management
33 techniques that will minimize the generation of infectious waste as well as the potential
34 for exposure to the public and employees.

35 (e) Generators shall keep records of infectious waste generated at their facility,
36 complete manifests required by the Commission to track waste, and ensure that wastes
37 are properly treated and disposed of according to regulations developed by the
38 Commission and the Department.

39 (f) Generators are responsible for assuring that the infectious waste they
40 generate is properly controlled, managed, treated, and disposed of according to
41 regulations promulgated under this Part. Generators shall be liable for treatment, clean-
42 up, and disposal costs created by the improper management of infectious waste if they
43 knew, or had reason to know, of the improper management. Generators are subject to
44 the penalties provided in G.S. 130A-310.24.

1 **"§ 130A-310.20. Containment; storage.**

2 (a) Infectious waste shall be isolated from other waste and contained in leak-
3 resistant sturdy containers of sufficient strength to prevent ripping, tearing, or bursting
4 under normal conditions. Sharps shall be handled separately and contained in sturdy,
5 rigid, and needle puncture-proof containers that are sealed to prevent loss of contents.

6 (b) All containers including infectious waste shall be clearly labeled with the
7 international biohazard symbol and warning signs to alert personnel and the public to
8 the contents of the container. Reusable containers shall be cleaned and disinfected after
9 each use.

10 (c) Infectious waste shall be stored in areas accessible only to authorized
11 personnel. Untreated infectious wastes may not be stored for longer than 24 hours
12 without refrigeration or treatment. In any case, storage times longer than 90 days are
13 prohibited. The Commission shall develop minimum requirements concerning
14 conditions of storage, time periods, and access control.

15 **"§ 130A-310.21. Transportation.**

16 (a) Infectious wastes may not be transported by trash chutes or other
17 conveyance where equipment contamination is possible.

18 (b) Transportation of infectious waste for off-site treatment or disposal shall
19 be completed by transporters licensed by the Department. The Department shall
20 implement a certification and licensing system to ensure that only qualified personnel
21 and vehicles meeting Department requirements transport infectious waste.

22 (c) Untreated infectious waste shall be transported in leak resistant, fully
23 enclosed containers within a vehicle equipped to contain potential spills. Infectious
24 waste may not be transported with noninfectious waste unless all waste in the load is
25 considered infectious. Infectious waste may not be transported in vehicles that will be
26 used to transport food or food products.

27 (d) Transporters may not accept infectious waste without receiving copies of
28 the properly completed manifest papers prepared by the generator, nor are they to
29 deliver wastes to a treatment or disposal facility unless that facility possesses a valid
30 operating permit.

31 **"§ 130A-310.22. Treatment and disposal.**

32 (a) Infectious waste shall be treated prior to disposal. Treatment technologies
33 include incineration, steam sterilization, and chemical disinfection. Treatment facilities
34 shall:

- 35 (1) Be approved by the Department,
36 (2) Meet or exceed minimum standards developed by the Department, and
37 (3) Obtain an operating permit prior to initiating treatment or disposal of
38 infectious waste.

39 (b) Incineration of infectious waste shall be completed in controlled-air,
40 multi-chambered incinerators with a minimum operating temperature of 1400 to 1600
41 degrees Fahrenheit in the primary chamber and 1800 degrees Fahrenheit in the secondary
42 chamber and a minimum 1.5 second residence time in the secondary chamber.
43 Operations and control technologies shall ensure that waste combustion to mineralized
44 ash is complete and that the production and emission of toxic air pollutants is

1 minimized. Incinerators shall be equipped with best available control technology and
2 meet standards developed by the Department.

3 (c) Autoclaving of infectious waste shall be conducted according to standards
4 that ensure that pathogenic organisms are destroyed or rendered harmless.
5 Chemotherapeutic and pathological waste, and animal carcasses shall not be steam
6 sterilized as a treatment method. Steam sterilization shall be accomplished by
7 subjecting the waste to a temperature of 250 degrees Fahrenheit for a period of not less
8 than 45 minutes. The Department shall develop and implement written operating
9 parameters and procedures to account for differing load conditions, characteristics of the
10 waste, and biological properties of the organisms. The generator shall develop and
11 implement a quality assurance program that includes provisions for calibration,
12 acceptance testing, use of heat sensitive tape and biological indicator microorganisms,
13 records of operations, loadings, and test documentation to assure complete sterilization.
14 Waste treated by steam sterilization shall be clearly and unambiguously labeled to
15 distinguish it from untreated waste.

16 (d) Chemical disinfection shall be used for large equipment, spill areas, or
17 containers not suited for steam sterilization or incineration. Chemical treatment shall be
18 completed under controlled conditions. Equipment used during the process is to be
19 tested for efficacy and safety.

20 (e) Sharps treated using sterilization shall be rendered mechanically harmless
21 prior to disposal.

22 (f) Treatment and disposal operators may not accept infectious waste shipments,
23 treated or untreated, without receiving copies of the properly completed manifest
24 papers.

25 (g) Treated infectious waste shall be disposed of in permitted facilities, or in the
26 case of liquid wastes, discharged to a sewer system with the approval of local
27 wastewater treatment management.

28 (h) Operators of treatment facilities shall certify that the waste was properly
29 treated and disposed of in accordance with State regulations. Certifications shall be
30 signed by a responsible person and forwarded to the generator responsible for the waste.

31 **"§ 130A-310.23. Registration, training, and certification.**

32 (a) The Commission shall implement a program to register infectious waste
33 generators and the Department shall approve and license transporters and permit
34 treatment facilities. The Commission and the Department shall establish standards
35 applicable to each of the above classes that include training and certification
36 requirements for operators, equipment and vehicles standards, treatment and testing
37 standards, and financial assurance standards for transporters and treatment facility
38 operators. Financial assurance requirements shall ensure adequate availability of funds
39 to cover cleanup, treatment, disposal, and liability claims associated with improper
40 waste handling, treatment, and disposal.

41 **"§ 130A-310.24. Violations; penalties.**

42 (a) In addition to any administrative action authorized by Part 2 of Article 1
43 of this Chapter, the Department may impose a fine not to exceed five hundred dollars
44 (\$500.00) for each violation of any provision of this Part or any rule promulgated

1 pursuant to this Part, and not to exceed two thousand five hundred dollars (\$2,500) for
2 any day. Each day that a violation continues may constitute a separate violation.

3 (b) In determining the amount of an administrative fine to be imposed for a
4 violation pursuant to subsection (a) of this section, the following factors shall be
5 considered:

6 (1) The gravity of the violation, including the probability that death or
7 serious physical or emotional harm to any person will result or has
8 resulted, the severity of the actual or potential harm, and the extent to
9 which the rule or the provisions of this Part were violated.

10 (2) Actions taken by the owner or operator to correct violations.

11 (3) Any previous violations.

12 (c) A person who violates any provision of this Part or any rule promulgated
13 pursuant to this Part is guilty of a misdemeanor punishable by a fine of five hundred
14 dollars (\$500.00) or imprisonment for a term not to exceed 60 days, or both."

15 Sec. 2. (a) Within 90 days after the date of ratification of this act, the
16 Commission and the Department shall jointly develop appropriate regulations and
17 standards to implement the requirements of this act.

18 (b) Within 90 days after the date of ratification of this act, the Department shall
19 develop appropriate regulations and standards relating to permitting transportation,
20 treatment, and disposal facilities, emissions control of infectious waste incinerators, and
21 pretreatment standards for discharges to municipal wastewater treatment facilities.

22 Sec. 3. Nothing in this act pertains to, or is intended to apply to, the practice
23 of veterinary medicine, animal husbandry, agriculture, or the production of
24 pharmaceuticals or biologicals, or vaccines for any of these.

25 Sec. 4. There is appropriated from the General Fund to the Department of
26 Human Resources the sum of five hundred thousand dollars (\$500,000) for the 1989-90
27 fiscal year to implement the provisions of this act.

28 Sec. 5. This act shall become effective July 1, 1989.