Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 06 DISEASES

Chapter 06 Communicable Disease Prevention—Handling, Treatment, and Disposal of Special Medical Waste

Authority: Health-General Article, §18-102, Annotated Code of Maryland

.01 Scope and Purpose.

A. Scope.

(1) Regulations .01—.03 apply to a person who generates and handles special medical waste or sharps.

(2) Regulations .01—.07 apply to a person who treats and disposes of special medical waste.

(3) This chapter does not apply to:

(a) Waste generated from veterinary practices that is governed by COMAR 15.14.03.02;

(b) Radioactive medical waste that is governed by COMAR 26.12.01.01;

(c) Remains of a dead human; and

(d) Fetuses and placentas that are released to a funeral director or a parent.

B. Purpose. The purpose of this chapter is to minimize the possibility of disease transmission by establishing requirements for the handling, treatment, and disposal of special medical waste.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Anatomical material" means human or animal body parts, including tissues and organs.

(2) "Autoclaving" means a process by which an article is subjected to steam under pressure for documented periods of time, temperature, and pressure that render the article incapable of transmitting disease to humans.

(3) "Blood" means human blood, human blood components, and products made from human blood.

(4) Bloodborne Pathogens.

(a) "Bloodborne pathogens" means pathogenic microorganisms that:

(i) Are present in human blood; and

(ii) Can cause disease in humans.

(b) "Bloodborne pathogens" includes, but is not limited to:

(i) Human immunodeficiency virus;

(ii) Hepatitis B virus; and

(iii) Hepatitis C virus.

(5) "Chemical disinfection" means the application of a chemical agent to an article, so that the article is rendered incapable of transmitting disease to humans.

(6) "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

(7) "Cremation" means the incineration of human or animal remains.

(8) "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on an article to render the article incapable of transmitting disease to humans.

(9) "Department" means the Department of Health and Mental Hygiene.

(10) "Disinfection" means a method that inactivates:

(a) Vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 log reduction or greater; and

(b) Bacillus stearothermophilus spores and Bacillus subtilis spores at a 4 log reduction or greater.

(11) "Encapsulation" means a process by which:

(a) An article is sealed in a material that renders the article no longer recognizable or capable of transmitting disease to humans; and

(b) The sealed material:

(i) Is decontaminated or disinfected during the encapsulation process; and

(ii) Remains sealed under physical stress.

(12) "Incineration" means a process during which an article is burned:

(a) In an incinerator that meets the requirements of the Department of the Environment as set forth in COMAR 26.11.08;

(b) To carbonized or mineralized ash that is capable of disposal as solid waste; and

(c) So the article is rendered incapable of transmitting disease to humans.

(13) "Infectious agent" means an organism, including viral, rickettsial, bacterial, fungal, protozoal, or helminthic, that is capable of producing infection or infectious disease in humans.

(14) "Interment" means burial in a location, other than a landfill, that is approved for that purpose under applicable law.

(15) "Mechanical destruction" means a physical process that renders an article no longer recognizable as the original article.

(16) "Microbiological laboratory waste" means waste from a microbiological laboratory that:

(a) Contains an infectious agent; and

(b) Includes cultures and stocks of infectious agents and associated biologicals.

(17) "Occupational exposure" means skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials, that results from the performance of an employee's duties.

(18) "Other potentially infectious material" means:

(a) The following human body fluids:

(i) Amniotic fluid;

(ii) A body fluid that is visibly contaminated with blood;

(iii) A body fluid that cannot be readily identified;

(iv) Cerebrospinal fluid;

(v) Pericardial fluid;

(vi) Peritoneal fluid;

(vii) Pleural fluid;

(viii) Saliva only when dental procedures are performed;

(ix) Semen;

(x) Synovial fluid; and

(xi) Vaginal secretions;

(b) A tissue or organ from a living or dead human, not including intact skin, that has not been preserved by a chemical additive or preservative;

(c) The following human immunodeficiency virus, hepatitis B virus, or hepatitis C virus related items:

(i) HIV containing cell, tissue, or organ cultures;

(ii) HIV, Hepatitis B, or Hepatitis C containing media or other solutions; and

(iii) Blood, organs, or other tissues; and

(d) Microbiological laboratory waste.

(19) "Person" means an individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity.

(20) "Sanitary sewer" means:

(a) A liquid waste piping network leading to a sewerage system permitted under Environment Article, §9-204, Annotated Code of Maryland; or

(b) An on-site sewerage system permitted under Environment Article, §9-204, Annotated Code of Maryland.

(21) "Sharps" means an object contaminated by blood or other potentially infectious material that can cut or penetrate the skin, including but not limited to:

(a) A broken capillary tube;

(b) Broken glass;

(c) An exposed end of dental wire;

(d) A needle;

(e) A surgical instrument; and

(f) A syringe with an attached sharp.

(22) "Special medical waste" means:

(a) Liquid or semiliquid blood or another potentially infectious material;

(b) A contaminated article that releases liquid or semiliquid blood or another potentially infectious material if compressed;

(c) An article that contains dried blood or another potentially infectious material and is capable of releasing the blood or material during handling;

(d) Pathological and microbiological waste containing blood or another potentially infectious material;

(e) Contaminated sharps; and

(f) Anatomical material.

.03 Handling of Special Medical Waste.

A person shall handle special medical waste in accordance with the requirements of:

A. 29 CFR §1910.1030(d)(4)(iii)(A) and (B), which is incorporated by reference at COMAR 09.12.31; and

B. COMAR 26.13.12.05 and 26.13.13.

.04 Treatment of Special Medical Waste, Excluding Sharps, Before Disposal.

A. Except as provided in §B of this regulation, a person shall:

(1) Treat special medical waste, excluding sharps, before disposal; and

(2) Use one of the following treatment methods:

(a) Autoclaving;

(b) Chemical disinfection;

(c) Cremation;

(d) Disinfection;

(e) Mechanical destruction after decontamination;

(f) Incineration; or

(g) An alternative method that meets the criteria of Regulation .06 of this chapter.

B. A person may discharge certain special medical waste directly into a sewerage system, without treatment, in accordance with Regulation.07B of this chapter.

.05 Treatment of Sharps Before Disposal.

A person shall treat sharps:

A. Before disposal; and

B. By one of the following methods:

(1) Encapsulation;

(2) Incineration;

(3) Mechanical destruction after decontamination; or

(4) An alternative method that meets the criteria of Regulation .06 of this chapter.

.06 Alternative Treatment Systems.

A. Except as provided in §B of this regulation, a person may not use a method for treatment of special medical waste other than those set forth at Regulations .04A(2) and .05B of this chapter.

B. Criteria for Alternative Treatment System. A person may use a method for treatment of special medical waste that complies with the following standards for treatment and microbial test procedures:

(1) The method inactivates vegetative bacteria, fungi, parasites, lipophilic or hydrophilic viruses, and mycobacteria at a 6 log reduction or greater;

(2) The method inactivates bacterial spores at a 4 log reduction or greater; and

(3) The tests have been performed on a representative from each of the following microbial groups:

(a) Staphylococcus aureus (ATCC 6538) or Pseudomonas aeruginosa (ATCC 15422);

(b) Candida albicans (ATCC 18804) or Penicillium chrysogenum (ATCC 24791);

(c) Polio 2 or Polio 3 or MS-2 Bacteriophage, (ATCC 15597-B1);

(d) Cryptosporidium spp. oocysts or Giardia spp. cysts;

(e) Mycobacterium terrae, Mycobacterium phlei, or Mycobacterium bovis (BCG) (ATCC 35743); and

(f) Bacillus stearothermophilus (ATCC 7953) or Bacillus subtilis (ATCC 19659).

C. A person may not use a method for treating of special medical waste that:

(1) Creates a threat to health or safety; or

(2) Violates applicable federal and State environmental laws or regulations.

.07 Disposal of Special Medical Waste.

A. Subject to §§B and C of this regulation, a person shall dispose of special medical waste after treatment by one of the following methods:

(1) Interment;

(2) Depositing in a facility approved to accept the type of solid waste being disposed in accordance with §C of this regulation; or

(3) Incineration.

B. A person may discharge a special medical waste that is liquid, semiliquid, or anatomical material that has been mechanically destroyed into a sewerage system, if the discharge is allowed under:

(1) Local ordinance or regulation; and

(2) Environment Article, Title 9, Annotated Code of Maryland.

C. A person shall dispose of special medical waste in accordance with:

(1) State laws and regulations pertaining to solid waste disposal including Environment Article, Title 9, Annotated Code of Maryland; and

(2) Local ordinances and regulations to the extent that the local requirements are not preempted by or in conflict with State law.

.08 Enforcement.

A. The Secretary may enter the property of any person who generates, handles, treats, or disposes of special medical waste to investigate a complaint the Secretary receives regarding the handling, treatment, or disposal of special medical waste.

B. Criminal Penalties.

(1) A person who violates these regulations is guilty of a misdemeanor, and on conviction is subject to a fine not exceeding $500.

(2) Each day that a violation exists shall constitute a separate offense.

C. In addition to any penalty under §B, if a person violates these regulations, the Secretary may suspend or revoke any license, permit, or certificate issued to the person under the Health-General Article, Annotated Code of Maryland.