

MEDICAL WASTE MANAGEMENT ACT

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**CALIFORNIA HEALTH AND SAFETY CODE
SECTIONS 117600 - 118360**

**CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
MEDICAL WASTE MANAGEMENT PROGRAM
1616 CAPITOL AVENUE, MS-7405
P. O. Box 997377
SACRAMENTO, CA 95899-7377**

Medical Waste Management Act

California Health and Safety Code

Sections 117600 – 118360

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Chapter 1 - General Provisions

117600 - Citation of Part

This part shall be known and may be cited as the Medical Waste Management Act.

117605 - Preempt

(a) This part governs medical waste management at the facility where waste is generated, at transfer stations, and at treatment facilities. This part also governs the tracking of medical waste beyond what is required in federal shipping documents and regulates aspects of the transport of regulated medical waste.

(b) Sections 173.196 and 173.197 of Title 49 of the Code of Federal Regulations impose standards for the transportation of medical waste on public roads and highways while in transport, unless an affected person applies to, and receives a determination of any perceived conflict from, the United States Secretary of Transportation. Domestic Mail Manual 601.10.17.5 (Mailability: Hazardous Materials: Sharps and Other Mailable Regulated Medical Waste) imposes standards for the transportation of medical waste through the mail and approves medical waste mail back systems.

(c) The department shall submit to the Legislature by no later than January 1, 2016, a report describing the interaction of federal and state law for the transport of regulated medical waste. The department shall convene a stakeholder group that includes, but is not limited to, small and large quantity generators, haulers, transfer station operators, treatment facility operators, local enforcement agencies, retailers, and other affected entities for this purpose. The reporting requirement imposed by this subdivision shall expire as of January 1, 2016, or when the report is submitted to the Legislature. The report submitted pursuant to this section shall be submitted in compliance with Section 9795 of the Government Code.

(d) The department may, in its discretion, update standards related to the transportation of medical waste during transit through a guidance document provided to regulated entities and posted on the department's Internet Web site. This guidance document shall be exempt from the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to the extent that the department finds that the updated standards are consistent with the standards of the United States Department of Transportation.

(e) If an affected person, including the department, seeks a preemption determination pursuant to Section 525 of Title 49 of the United States Code or by a court of competent jurisdiction, the department may, in its discretion, temporarily waive the state transportation requirements under this part until that determination is made and shall provide notice of the waiver on its Internet Web site.

(f) During the period of temporary waiver described in subdivision (e), or if preemption is found, the federal requirements shall be deemed to be the law of this state and enforceable by the department. The department may enforce these federal requirements

by providing an updated guidance document to interested parties and posting the updated guidance document on the department's Internet Web site.

(g) The Medical Waste Management Act does not preempt any local ordinance regulating infectious waste, as that term was defined by Section 25117.5 as it read on December 31, 1990, if the ordinance was in effect on January 1, 1990, and regulated both large and small quantity generators. Any ordinance may be amended in a manner that is consistent with this part.

117610 - Regulations

The department shall adopt regulations that will establish and ensure statewide standards for uniformity in the implementation and administration of this part and that will promote waste minimization and source reduction.

117615 - Local Ordinance

Notwithstanding Section 117605, with the approval of the director, and in the interest of public health, a local ordinance providing more stringent requirements than specified in this part may be implemented for a specified time period.

Chapter 2 - Definitions

117625 - Definitions

Unless the context requires otherwise, the definitions in this article govern the construction of this part.

117630 - Biohazard Bag

"Biohazard bag" means a disposable film bag that is impervious to moisture. The film bags that are used for transport shall be marked and certified by the manufacturer as having passed the tests prescribed for tear resistance in the American Society for Testing Materials (ASTM) D1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method" and for impact resistance in ASTM D1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method," as those documents were published on January 1, 2014. The film bag shall meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both parallel and perpendicular planes with respect to the length of the bag. The color of the bag shall be red, except when yellow bags are used to further segregate trace chemotherapy waste and white bags are used to further segregate pathology waste.

117636 – Chemotherapeutic Agent

"Chemotherapeutic agent" means an agent that kills or prevents the reproduction of malignant cells. Chemotherapeutic agent excludes anti-inflammatory and antibiotic medications used to treat malignant cells in the practice of veterinary medicine.

117637 - Common Carrier

"Common carrier" means either of the following:

(a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.

(b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.

117640 - Common Storage Facility

“Common storage facility” means any designated accumulation area that is onsite and is used by small quantity generators otherwise operating independently for the storage of medical waste for collection by a registered hazardous waste hauler.

117645 - Container

“Container” means the rigid container in which the medical waste is placed prior to transporting for purposes of storage or treatment.

117647 – Empty

“Empty” means a condition achieved when tubing, a container, or inner liner removed from a container that previously contained liquid or solid material, including, but not limited to, a chemotherapeutic agent, is considered empty. The tubing, container, or inner liner removed from the container shall be considered empty if it has been emptied so that the following conditions are met:

- (a) If the material that the tubing, container, or inner liner held is pourable, no material can be poured or drained from the tubing, container, or inner liner when held in any orientation, including, but not limited to, when tilted or inverted.
- (b) If the material that the container or inner liner held is not pourable, no material or waste remains in the container or inner liner that can feasibly be removed by scraping.

117650 - Enforcement Agency

“Enforcement agency” means the department or the local agency administering this part.

117655 - Enforcement Officer

“Enforcement officer” means the director, or agents or registered environmental health specialists appointed by the director, and all local health officers, directors of environmental health, and their duly authorized registered environmental health specialists and environmental health specialist trainees, or the designees of the director, local health officers, or the directors of environmental health.

117657 - Fund

“Fund” means the Medical Waste Management Fund created pursuant to Section 117885.

117660 - Hazardous Waste Hauler

“Hazardous waste hauler” means a person registered as a hazardous waste hauler pursuant to Article 6 (commencing with Section 25160) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20 and Chapter 30 (commencing with Section 66001) of Division 4 of Title 22 of the California Code of Regulations.

117662 - Health Care Professional

“Health care professional” means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act, as set forth in Chapter 8 (commencing with Section 3600) of Division 2 of the Business and Professions Code, or pursuant to the Chiropractic Initiative Act, as set forth in Chapter 2 (commencing with Section 1000) of Division 2 of the Business and Professions Code; and any person certified pursuant to Division 2.5 (commencing with Section 1797).

117665 - Highly Communicable Diseases

“Highly communicable diseases” means diseases, such as those caused by organisms classified by the federal Centers for Disease Control and Prevention as risk group 3 organisms or higher.

117670 - Household Waste

“Household waste” means any material, including garbage, trash, and sanitary wastes in septic tanks and medical waste, that is derived from households, farms, or ranches. Household waste does not include trauma scene waste.

117671 – Home-generated Sharps Waste

“Home-generated sharps waste” means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.

117672 - Industrial Hygienist

“Industrial hygienist” means a person who has met the educational requirements of an industrial hygiene certification organization, as defined in subdivision (c) of Section 20700 of the Business and Professions Code, and who has had at least one year in the comprehensive practice of industrial hygiene, as defined in subdivision (a) of Section 20700 of the Business and Professions Code.

117675 - Infectious Agent

“Infectious agent” means a type of microorganism, bacteria, mold, parasite, or virus, including, but not limited to, organisms managed as Biosafety Level II, III, or IV by the federal Centers for Disease Control and Prevention, that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

117680 - Large Quantity Generator

“Large quantity generator” means a medical waste generator, other than a trauma scene waste management practitioner, that generates 200 or more pounds of medical waste in any month of a 12-month period.

117685 - Local Agency

“Local agency” means the local health department, as defined in Section 101185, or the local comprehensive environmental agency established in accordance with Section 101275, of a county that has elected to adopt a local ordinance to administer and enforce this part, pursuant to Chapter 3 (commencing with Section 117800).

117690 - Medical Waste

(a) “Medical waste” means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes. Biohazardous, pathology, pharmaceutical, sharps, and trace chemotherapy wastes that meet the conditions of this section are not subject to any of the hazardous waste requirements found in Chapter 6.5 (commencing with Section 25100) of Division 20.

(b) For purposes of this part the following definitions apply:

(1) “Biohazardous waste” includes all of the following:

(A) (i) Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human or from an animal that is suspected by the attending veterinarian of being infected with a pathogen that is also infectious to humans, which includes diagnosis and immunization; or from biomedical research, which includes the production and testing of biological products.

(ii) Regulated medical waste or clinical waste or biomedical waste suspected of containing a highly communicable disease.

(B) Laboratory waste such as human specimen cultures or animal specimen cultures that are infected with pathogens that are also infectious to humans; cultures and stocks of infectious agents from research; wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis and Contagious Ecthyma, as defined

by the department; culture dishes, devices used to transfer, inoculate, and mix cultures; and wastes identified by Section 173.134 of Title 49 of the Code of Federal Regulations as Category B “once wasted” for laboratory wastes.

(C) Waste that, at the point of transport from the generator’s site or at the point of disposal contains recognizable fluid human blood, fluid human blood products, containers, or equipment containing human blood that is fluid, or blood from animals suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(D) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans or animals that are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or diseases of animals that are communicable to humans.

(2) Pathology waste includes both of the following:

(A) Human body parts, with the exception of teeth, removed at surgery and surgery specimens or tissues removed at surgery or autopsy that are suspected by the health care professional of being contaminated with infectious agents known to be contagious to humans or having been fixed in formaldehyde or another fixative.

(B) Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(3) “Pharmaceutical waste” means a pharmaceutical, as defined in Section 117747, including trace chemotherapy waste, that is a waste, as defined in Section 25124. For purposes of this part, “pharmaceutical waste” does not include a pharmaceutical that meets either of the following criteria:

(A) The pharmaceutical is being sent out of the state to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.

(B) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and

Professions Code and as a permitted transfer station if the reverse distributor is located within the state.

(4) "Sharps waste" means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste.

(5) "Trace chemotherapeutic waste" means waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, including, but not limited to, gloves, disposable gowns, towels, and intravenous solution bags and attached tubing that are empty. A biohazardous waste that meets the conditions of this paragraph is not subject to the hazardous waste requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

(6) "Trauma scene waste" means waste that is a regulated waste, as defined in Section 5193 of Title 8 of the California Code of Regulations, and that has been removed, is to be removed, or is in the process of being removed, from a trauma scene by a trauma scene waste management practitioner.

117695 - Treated Medical Waste

Medical waste that has been treated in accordance with the provisions of the Medical Waste Management Act, Chapter 8 (commencing with Section 118215), and that is not otherwise hazardous, shall thereafter be considered solid waste as defined in Section 40191 of the Public Resources Code and not medical waste.

117700 - Not Medical Waste

Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675, or an agent capable of causing an infection that is highly communicable, as defined in Section 117665.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans or a highly communicable disease.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains visible or recognizable fluid blood, as provided in subparagraph (C) of paragraph (1) of subdivision (b) of Section 117690.

- (d) Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.
- (e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671.
- (f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch unless otherwise specified in law.

117705 - Medical Waste Generator

“Medical waste generator” means any person whose act or process produces medical waste and includes, but is not limited to, a provider of health care, as defined in subdivision (d) of Section 56.05 of the Civil Code. All of the following are examples of businesses that generate medical waste:

- (a) Medical and dental offices, clinics, hospitals, surgery centers, laboratories, research laboratories, unlicensed health facilities, those facilities required to be licensed pursuant to Division 2 (commencing with Section 1200), chronic dialysis clinics, as regulated pursuant to Division 2 (commencing with Section 1200), and education and research facilities.
- (b) Veterinary offices, veterinary clinics, and veterinary hospitals.
- (c) Pet shops.
- (d) Trauma scene waste management practitioners.

117710 - Medical Waste Management Plan

“Medical waste management plan” means a document that is completed by generators of medical waste that describes how the medical waste generated at their facility shall be segregated, handled, stored, packaged, treated, or shipped for treatment, as applicable, pursuant to Section 117935 for small quantity generators and Section 117960 for large quantity generators, on forms prepared by the enforcement agency, if those forms are provided by the enforcement agency.

117715 - Medical Waste Permit

“Medical waste permit” means a permit issued by the enforcement agency to a medical waste treatment facility.

117720 - Medical Waste Registration

“Medical waste registration” means a registration issued by the enforcement agency to a medical waste generator.

117725 - Medical Waste Treatment Facility

(a) "Medical waste treatment facility" means all land and structures, and other appurtenances or improvements on the land under the control of the treatment facility, used for treating medical waste offsite from a medical waste generator, including associated handling and storage of medical waste as permitted by the department.

(b) For purposes of this section, land is under the control of the treatment facility if it is owned, rented, or controlled by contractual agreement.

117730 - Mixed Waste

"Mixed waste" means mixtures of medical and nonmedical waste. Mixed waste is medical waste, except for all of the following:

(a) Medical waste and hazardous waste is hazardous waste and is subject to regulation as specified in the statutes and regulations applicable to hazardous waste.

(b) Medical waste and radioactive waste is radioactive waste and is subject to regulation as specified in the statutes and regulations applicable to radioactive waste.

(c) Medical waste, hazardous waste, and radioactive waste is radioactive mixed waste and is subject to regulation as specified in the statutes and regulations applicable to hazardous waste and radioactive waste.

117735 - Offsite

"Offsite" means any location that is not onsite.

117740 - Onsite

(a) "Onsite" means a medical waste treatment facility, or common storage facility on the same or adjacent property as the generator of the medical waste being treated.

(b) "Adjacent," for purposes of subdivision (a), means real property within 400 yards from the property boundary of the existing medical waste treatment facility.

117742 - Parent Organization

"Parent organization" means an organization that employs or contracts with health care professionals who provide health care services at a location other than at a health care facility specified in subdivision (a) of Section 117705.

117745 - Person

"Person" means an individual, trust, firm, joint stock company, business concern, partnership, association, limited liability company, and corporation, including, but not limited to, a government corporation. "Person" also includes any city, county, district, commission, the state or any department, agency, or political subdivision thereof, the Regents of the University of California, any interstate body, and the federal government or any department or agency thereof to the extent permitted by law.

117747 - Pharmaceutical

(a) "Pharmaceutical" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321(g)(1)).

(b) For purposes of this part, "pharmaceutical" does not include any pharmaceutical that is regulated pursuant to either of the following:

(1) The federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C.A. Sec. 6901 et seq.). This waste stream shall be handled as a hazardous waste under the authority of Chapter 6.5 (commencing with Section 25100) of Division 20.

(2) The Radiation Control Law (Chapter 8 [commencing with Section 114960] of Part 9).

117750 - Sharps Container

(a) "Sharps container" means a rigid puncture-resistant container used in patient care or research activities meeting the standards of, and receiving approval from, the United States Food and Drug Administration as a medical device used for the collection of discarded medical needles or other sharps.

(b) Sharps containers, including those used to containerize trace chemotherapeutic wastes, shall not be lined with a plastic bag or inner liner.

117760 - Small Quantity Generator

"Small quantity generator" means a medical waste generator, other than a trauma scene waste management practitioner, that generates less than 200 pounds per month of medical waste.

117765 - Storage

"Storage" means the holding of medical wastes, in compliance with the Medical Waste Management Act, including Chapter 9 (commencing with Section 118275), at a designated accumulation area, offsite point of consolidation, transfer station, other registered facility, or in a vehicle detached from its means of locomotion.

117770 - Tracking Document

"Tracking document" means the medical waste tracking document specified in Section 118040.

117771 – Shipping Document

"Shipping document" means the medical waste shipping document required by the United States Department of Transportation pursuant to Section 172.200 et seq. of Title 49 of the Code of Federal Regulations or the document required by the United States Postal Service pursuant to Domestic Mail Manual 601.10.17.5 (Mailability: Hazardous Materials: Sharps and Other Mailable Regulated Medical Waste).

117775 - Transfer Station

(a) "Transfer station" means an offsite location permitted by the department where medical waste is loaded, unloaded, stored, or consolidated by a registered hazardous waste hauler during the normal course of transportation of the medical waste.

(b) "Transfer station" does not include any onsite facility, including, but not limited to, common storage facilities, facilities of medical waste generators employed for the purpose of consolidation, or onsite treatment facilities.

117776 - Trauma Scene.

(a) "Trauma scene" means a location soiled by, or contaminated with, human blood, human body fluids, or other residues from the scene of a serious human injury, illness, or death.

(b) For purposes of this section, a location may include, but is not limited to, a physical structure that is not fixed geographically, such as mobile homes, trailers, or vehicles.

117778 - Trauma Scene Waste Management Practitioner

"Trauma scene waste management practitioner" means a person who undertakes as a commercial activity the removal of human blood, human body fluids, and other associated residues from the scene of a serious human injury, illness, or death, and who is registered with the department pursuant to Chapter 9.5 (commencing with Section 118321).

117780 - Treatment

"Treatment" means any method, technique, or process designed to change or destroy the biological character or composition of any medical waste so as to eliminate its potential for causing disease or creating public or environmental harm, as specified in Chapter 8 (commencing with Section 118215).

Chapter 3 – Powers and Duties

117800 - Local Agency

A local agency may implement a medical waste management program by the adoption of an ordinance or resolution by the local governing body, in accordance with this part.

117805 - Notify Department

A local agency that elects to implement a medical waste management program shall notify the department of its intent to do so.

117810 - Implementation

(a) If a local agency does not elect to implement a medical waste management program, the local agency may elect to contract with another local agency to implement a medical waste management program or to implement it at a later date.

This election shall be made by the local governing body, that shall take effect 90 days after a notice of election is filed with the department.

(b) A local agency that elects to implement a medical waste management program shall continue to implement that program until the local governing body terminates the election by resolution or ordinance or the department revokes the authority of the local agency to administer a medical waste management program. The local agency shall file the notice of termination with the department at least 180 days prior to the termination date.

117815 - Program Consistency

Any local agency that has elected to implement a medical waste management program shall maintain a program that is consistent with Section 117820 and the regulations adopted pursuant to that section. With the approval of the department, the local agency may administer or enforce this part with respect to any person.

117820 - Medical Waste Management Program

A medical waste management program shall include, but not be limited to, all of the following:

- (a) Issuing medical waste registrations and permits pursuant the Medical Waste Management Act.
- (b) Processing and reviewing the medical waste management plans and inspecting onsite treatment facilities in accordance with Chapter 4 (commencing with Section 117925) for all small quantity medical waste generators required to be registered.
- (c) Conducting an evaluation, inspection, or records review for all facilities or persons issued a large quantity medical waste registration pursuant to Chapter 5 (commencing with Section 117950) or issued a permit for an onsite medical waste treatment facility pursuant to Chapter 7 (commencing with Section 118130).
- (d) Inspecting medical waste generators in response to complaints or emergency incidents, or as part of an investigation or evaluation of the implementation of the medical waste management plan.
- (e) Inspecting medical waste treatment facilities in response to a complaint or as part of an investigation or emergency incident.
- (f) Taking enforcement action for the suspension or revocation of medical waste permits issued by the local agency pursuant to this part.
- (g) Referring or initiating proceedings for civil or criminal prosecution of violations specified in Chapter 10 (commencing with Section 118335).
- (h) Reporting in a manner determined by the department so that the statewide effectiveness of the program can be determined.

117825 - Registration and Permit Fees

Each local enforcement agency that elects to implement the medical waste management program may prescribe, by resolution or ordinance, the registration and permit fees necessary to pay its reasonable expenses to administer the program.

117830 - Enforcement Agency

(a) A local agency electing to implement a medical waste management program is the enforcement agency for the jurisdiction where it is located and so designated by the department.

(b) In any local jurisdiction where the local agency does not elect to implement a medical waste management program, the department is the enforcement agency.

(c) Nothing in this chapter shall prevent a district attorney, city attorney, or city prosecutor from bringing any enforcement action for violation of this chapter.

117835 - Department's Database

The department shall establish and maintain a database of persons registered as small quantity generators and as large quantity generators for whom the department is the enforcement agency under Chapter 4 (commencing with Section 117925) and Chapter 5 (commencing with Section 117950).

117840 - Intent of the Legislature

It is the intent of the Legislature that the program carried out pursuant to this part be fully supported from the fees received pursuant to this part.

117845 - Department Shall Implement

The department shall implement this part so as to maximize the funds that may be received from the federal government.

117850 - Share Information

Information may be shared between the department and the Environmental Protection Agency.

117855 - Withdrawal

If the department finds that a local enforcement agency is not consistently fulfilling its responsibilities, the department shall notify the agency of the particular reasons for finding that the agency is not fulfilling its responsibilities and of the department's intention to withdraw its designation if, within a time to be specified in that notification, but in no event less than 30 days, the agency does not take the corrective action specified by the department.

117860 - Department Becomes Enforcement Agency

If the department withdraws its designation of a local enforcement agency, the department shall become the enforcement agency within the jurisdiction of the local enforcement agency.

117870 - Department Identifies Significant Violations

If the department identifies significant violations of minimum requirements that were not identified and resolved through previous inspections by the local enforcement agency, the department shall do all of the following:

- (a) Conduct a performance review of the agency within 120 days.
- (b) Prepare a written performance report within 60 days of the review.
- (c) Require the submission of a plan of correction by the agency within 90 days of receiving the report.

117875 - Withdrawal

The department shall withdraw a local enforcement agency's designation pursuant to Section 117860 if it determines that the enforcement agency has failed to submit an adequate plan of correction or has failed to implement the plan.

117880 - Fees

If the department becomes the enforcement agency, it may charge the fees specified in this part.

117885 - Fund

(a) There is in the State Treasury the Medical Waste Management Fund, that shall be administered by the director. Money deposited in the fund shall be available to the department, upon appropriation by the Legislature, for the purposes of this part.

(b) In addition to any other funds transferred by the Legislature to the Medical Waste Management Fund, the following shall be deposited in the fund:

- (1) Fees, penalties, interest earned, and fines collected by, or on behalf of, the department pursuant to this part.
- (2) Funds granted by the federal government for purposes of carrying out this part.

117890 - Large Quantity Generator (LQG) Registration

(a) No large quantity generator shall generate medical waste unless the large quantity generator is registered with the enforcement agency pursuant to this part.

(b) Registration pursuant to this part shall also allow the large quantity generator to generate medical waste at temporary events, including, but not limited to, health fairs, vaccination clinics, and veteran stand downs, without further registration or permitting required. The large quantity generator shall notify the local enforcement agency of their intended participation in a temporary event at least 72 hours before the event, unless the sponsor of the temporary event previously notified the local enforcement agency of the event.

117895 - Small Quantity Generator (SQG) Registration – Temporary Events

Registration pursuant to this part shall allow a small quantity generator to generate medical waste at temporary events, including, but not limited to, health fairs, vaccination clinics, and veteran stand downs, without further registration or permitting required. The small quantity generator shall notify the local enforcement agency of their intended participation in a temporary event at least 72 hours before the event, unless the sponsor of the temporary event previously notified the local enforcement agency of the event.

117900 - Medical Waste Hauler Registration

No person shall haul medical waste unless the person is one of the following:

- (a) A registered hazardous waste hauler pursuant to the requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.
- (b) A mail-back system approved by the United States Postal Service.
- (c) A common carrier allowed to haul pharmaceutical waste pursuant to Section 118029 or 118032.
- (d) A small quantity generator or large quantity generator transporting limited quantities of medical waste with an exemption granted pursuant to either Section 117946 or Section 117976, respectively.
- (e) A registered trauma scene waste practitioner hauling trauma scene waste pursuant to Section 118321.5.

117903 - Treat Medical Waste

No person shall treat medical waste unless the person is permitted by the enforcement agency as required by this part or unless the treatment is performed by a medical waste generator and is a treatment method approved pursuant to Chapter 8 (commencing with Section 118215).

117904 - Consolidation

- (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated sharps waste, which, after collection, shall be transported and treated as medical waste.
- (b) A consolidation location approved pursuant to this section shall be known as a “home-generated sharps consolidation point.”
- (c) A home-generated sharps consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275), to the permit or registration requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated sharps waste pursuant to this section.

(d) A home-generated sharps consolidation point shall comply with all of the following requirements:

(1) All sharps waste shall be placed in sharps containers.

(2) Sharps containers ready for disposal shall not be held for more than seven days without the written approval of the enforcement agency.

(e) An operator of a home-generated sharps consolidation point approved pursuant to this section shall not be considered the generator of that waste but shall be listed on the shipping document in compliance with United States Department of Transportation and United States Postal Service requirements.

(f) The medical waste treatment facility which treats the sharps waste subject to this section shall maintain the shipping and tracking documents required by Sections 118040 and 118165 with regard to that sharps waste.

117905 - Offsite Treatment

The department is the enforcement agency for offsite treatment facilities.

117908 - Common Storage Facility

The accumulated medical waste of more than one medical waste generator shall not be stored in a common storage facility unless that facility is registered with the enforcement agency.

117910 - Technical Assistance & Guidance

The department shall provide ongoing technical assistance and guidance to local enforcement agencies to assist them in their decision making processes. This assistance shall include, but is not limited to, providing all of the following:

(a) Technical studies and reports.

(b) Copies of innovative facility operation plans.

(c) Investigative findings and analysis of new waste management practices and procedures.

Chapter 4 - Small Quantity Generator Requirements

117915 - Containment and Storage

Containment and storage of medical waste shall be in accordance with Chapter 9 (commencing with Section 118275).

117918 - Treatment

Medical waste shall be treated using treatment technologies in accordance with Chapter 8 (commencing with Section 118215).

117920 - Registration

The fee schedule specified in Section 117923 shall be for the issuance of medical waste registrations and for conducting inspections pursuant to this chapter when the department serves as the enforcement agency for small quantity generators. This fee schedule shall be adjusted annually in accordance with Section 100425, or as provided in the regulations adopted by the department, not to exceed the reasonable regulatory costs of the department. Local enforcement agencies shall set fees that shall be sufficient to cover their costs in implementing this part with regard to small quantity generators required to be registered pursuant to Section 117925.

117923 - Fees

(a) The registration and inspection fee for small quantity generators using onsite treatment, including an autoclave, incinerator, or microwave technology, to treat medical waste is one hundred dollars (\$100), that shall be paid once every two years.

(b) The annual permit fee for a common storage facility permitted pursuant to Section 117928 is the amount specified in the following schedule:

(1) For storage facilities serving 10 or fewer generators, the permit fee is one hundred dollars (\$100).

(2) For storage facilities serving 11 or more generators, but not more than 50 generators, the permit fee is two hundred fifty dollars (\$250).

(3) For storage facilities serving more than 50 generators, the permit fee is five hundred dollars (\$500).

117924 - Collect Fees

(a) When the department is the enforcement agency, the department shall impose and cause the collection of an annual medical waste generator fee in an amount not to exceed twenty-five dollars (\$25) on small quantity generators of medical waste, except for those small quantity generators that are required to register pursuant to Section 117925 and those generators generating only pharmaceutical waste as defined in paragraph (3) of subdivision (g) of Section 117690. Nothing in this part shall prevent the department from contracting with entities other than the department for these fee collection activities or from entering into agreements with medical waste transporters for the collection of these fees, if the department determines that such a fee collection arrangement would be cost effective.

(b) If the department determines to enter into a contract with a medical waste transporter for the collection of the fees, the department shall do all of the following:

(1) Establish that not more than 7.5 percent of the fees collected may be recovered by the medical waste transporter as administrative costs for the collection of those fees.

- (2) Establish that the administrative costs for the collection of the fees shall be the same for all medical waste transporters.
- (3) Prohibit any medical waste transporter from waiving the generator fee without the written approval of the department and only if the medical waste generator has made a written request for the waiver.
- (4) Require the medical waste transporter to report the fees collected pursuant to subdivision (a) to the department.
- (5) Prohibit the medical waste transporter from assuming the role of the department as an enforcement agent for purposes of collecting the medical waste generator fees.
- (6) Require medical waste transporters to include the following language in at least 12-point type on their invoices to medical waste generators: "Pursuant to Section 117924 of the California Health and Safety Code, the State Department of Public Health has contracted with us to collect your annual medical waste generator fee. The department may offset our costs of collection and administration in an amount that may not exceed 7.5 percent of the fee collected. We may not waive the fee without written approval of the department, and only if you have made a written request for the waiver."
- (7) Ensure that generators subject to this section are required to pay the fee only once per year.

117925 - Onsite Treatment

- (a) Each small quantity generator using onsite steam sterilization, incineration, or microwave technology to treat medical waste shall register with the enforcement agency. Small quantity generators owning or operating a medical waste treatment facility shall also apply for a permit for that treatment facility pursuant to Chapter 7 (commencing with Section 118130).
- (b) Small quantity generators using onsite treatment, as specified in subdivision (a), that operate as a business in the same building, or that are associated with a group practice in the same building, may register as one generator.
- (c) Small quantity generators using onsite treatment, as specified in subdivision (a), as specified in subdivision (b), operating in different buildings on the same or adjacent property, or as approved by the enforcement agency, may register as one generator.
- (d) "Adjacent," for purposes of subdivision (c), means real property within 400 yards from the property boundary of the primary registration site.

117928 - Common Storage Facility

(a) Any common storage facility for the collection of medical waste produced by small quantity generators operating independently, but sharing common storage facilities, shall have a permit issued by the enforcement agency prior to the commencement of storage of medical waste in the common storage facility.

(b) A permit for any common storage facility specified in subdivision (a) may be obtained by any one of the following:

(1) A provider of health care as defined in subdivision (d) of Section 56.05 of the Civil Code.

(2) The registered hazardous waste transporter.

(3) The property owner.

(4) The property management firm responsible for providing tenant services to the medical waste generators.

117930 - Treat Onsite

Small quantity generators that treat waste onsite, pursuant to subdivision (a) of Section 117925, shall register with the enforcement agency prior to the commencement of treatment.

117935 - Medical Waste Management Plan

A small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan on forms prescribed by the enforcement agency, if provided. The plans shall contain, but are not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste.

(g) The name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, if applicable.

- (h) The name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032, if applicable.
- (i) If applicable, the steps taken to categorize the pharmaceutical wastes generated at the facility to ensure that the wastes are properly disposed of as follows:
- (1) Pharmaceutical waste classified by the federal Drug Enforcement Agency (DEA) as “controlled substances” are disposed in compliance with DEA requirements.
 - (2) The name and business address of the registered hazardous waste hauler used by the generator to have wastes that are not regulated pursuant to the federal Resource Conservation and Recovery Act of 1976 and nonradioactive pharmaceutical wastes regulated as medical waste safely removed for treatment in compliance with subdivision (b) of Section 118222 as waste requiring specific methods.
- (j) A closure plan for the termination of treatment at the facility using, at a minimum, one of the methods of decontamination specified in subdivision (a) or (b) of Section 118295, thereby rendering the property to an acceptable sanitary condition following the completion of treatment services at the site.
- (k) A statement certifying that the information provided is complete and accurate.

117938 - Biennial Inspection

- (a) Small quantity generators using onsite steam sterilization, incineration, or microwave technology to treat medical waste are subject to biennial inspection of that onsite treatment facility by the enforcement agency and may be subject to the permitting requirements for onsite medical waste treatment facilities as determined by the enforcement agency.
- (b)(1) The operators of the treatment equipment specified in subdivision (a) shall be required to receive training in the operation of the treatment equipment, proper protective equipment to wear, if any, how to clean up spills, and other information required to operate the equipment in a safe and effective manner.
- (2) Annual training for the operators shall be provided after the initial training has been completed.
- (3) The training shall be documented for each treatment operator and retained on file at the generator facility for a minimum of two years. Training shall comply with applicable federal Occupational Safety and Health Administration regulations, including those found in Section 1910 of Title 29 of the Code of Federal Regulations.

117940 - Medical Waste Generator Registration

- (a) Each enforcement agency shall follow procedures consistent with this chapter in registering medical waste generators.
- (b) Each medical waste generator registration for small quantity generators issued by the enforcement agency shall be valid for two years.
- (c) An application for renewal of the registration for small quantity generators shall be filed with the enforcement agency on or before the expiration date.
- (d) Generators shall submit an updated application form when any of the information specified in their medical waste management plan, created pursuant to Section 117935, changes. The updated application form shall be submitted within 30 days of the change.

117943 - Treatment and Tracking Records

- (a) A medical waste generator required to register pursuant to this chapter shall maintain for a minimum of three years individual treatment operating records, and if applicable, shipping and tracking documents for all untreated medical waste shipped offsite for treatment, and shall report or submit to the enforcement agency, upon request, all of the following:

- (1) Treatment operating records. Operating records shall be maintained in written or electronic form.
- (2) An emergency action plan complying with regulations adopted by the department.
- (3) Shipping and tracking documents or electronically archived shipping and tracking documents maintained by the facility and medical waste hauler of all untreated medical waste shipped offsite for treatment.

- (b) Documentation shall be made available to the enforcement agency onsite.

117945 - Information Documentation and Transportation Records

- (a) Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

- (1) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.
- (2) Records required by the United States Department of Transportation or the United States Postal Service of any medical waste shipped offsite for treatment and disposal. The small quantity generator shall maintain or have available electronically at the facility or from the medical waste hauler or common carrier, these records for not less than three years.

(b) Documentation shall be made available to the enforcement agency onsite.

117946 - Materials of Trade Exemption

(a) A small quantity medical waste generator or parent organization that employs health care professionals who generate medical waste may transport medical waste generated in limited quantities up to 35.2 pounds to the central location of accumulation, provided that all of the following are met:

(1) The principal business of the generator is not to transport or treat regulated medical waste.

(2) The generator shall adhere to the conditions and requirements set forth in the materials of trade exception, as specified in Section 173.6 of Title 49 of the Code of Federal Regulations.

(3) A person transporting medical waste pursuant to this section shall provide a form or log to the receiving facility, and the receiving facility shall maintain the form or log for a period of two years, containing all of the following information:

(A) The name of the person transporting the medical waste.

(B) The number of containers of medical waste transported.

(C) The date the medical waste was transported.

(b) A generator transporting medical waste pursuant to this section shall not be regulated as a hazardous waste hauler pursuant to Section 117660.

Chapter 5 - Large Quantity Generator Requirements

117950 - Registration

(a) Each large quantity generator, except as specified in subdivisions (b) and (c), shall register with the enforcement agency prior to commencement of the generation of medical waste.

(b) Large quantity generators operating as a business in the same building, or that are associated with a group practice in the same building, may register as one generator.

(c) Large quantity generators as specified in subdivision (a), operating in different buildings on the same or adjacent property, or as approved by the enforcement agency, may register as one generator.

(d) "Adjacent," for purposes of subdivision (c), means real property within 400 yards from the property boundary of the primary registration site. All federal transportation requirements specified in Section 173.6 of Part 49 of the Code of Federal Regulations shall apply for purposes of transporting medical waste from adjacent properties.

117960 - Medical Waste Management Plan

A large quantity generator required to register with the enforcement agency shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency, if provided. The plans shall contain, but are not limited to, all of the following:

- (a) The name of the person.
- (b) The business address of the person.
- (c) The type of business.
- (d) The types, and the estimated average monthly quantity, of medical waste generated.
- (e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, the treatment capacity of the onsite treatment facility.
- (f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.
- (g) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.
- (h) An emergency action plan complying with regulations adopted by the department.
- (i) If applicable, the steps taken to categorize the pharmaceutical wastes generated at the facility to ensure that the wastes are properly disposed of as follows:
 - (1) Pharmaceutical waste classified by the federal Drug Enforcement Agency (DEA) as "controlled substances" are disposed in compliance with DEA requirements.
 - (2) The name and business address of the hazardous waste hauler used by the generator to have wastes that are not regulated pursuant to the federal Resource Conservation and Recovery Act of 1976 and nonradioactive pharmaceutical wastes regulated as medical waste safely removed for treatment in compliance with subdivision (b) of Section 118222 as waste requiring specific methods.
- (j) A closure plan for the termination of treatment at the facility using, at a minimum, one of the methods of decontamination specified in subdivision (a) or (b) of Section 118295, thereby rendering the property to an acceptable sanitary condition following the completion of treatment services at the site.

- (k) A statement certifying that the information provided is complete and accurate.

117965 - Annual Inspection

Large quantity generators shall be subject to at least annual inspection by the enforcement agency.

117967 – Onsite Treatment

(a) Large quantity generators that treat medical waste onsite using steam sterilization, incineration, microwave technology, or other department approved treatment technology to treat medical waste shall train the operators of the equipment in its use, proper protective equipment to wear, if necessary, and how to clean up spills to ensure that the equipment is being operated in a safe and effective manner.

(b) Annual training for the operators shall be provided after the initial training has been completed.

(c) The training shall be documented and the documentation shall be retained at the facility for a minimum of two years. Training shall comply with applicable federal Occupational Safety and Health Administration regulations, including those found in Section 1910 of Title 29 of the Code of Federal Regulations.

117970 - Medical Waste Generator Registration

(a) Each enforcement agency shall follow procedures consistent with this chapter in registering medical waste generators.

(b) Each medical waste registration issued by the enforcement agency for large quantity generators shall be valid for one year.

(c) An application for renewal of the registration shall be filed with the enforcement agency not less than 90 days prior to the expiration date. Failure to meet this requirement shall result in an assessment of a late fee.

(d) Generators shall update their medical waste management plan, established pursuant to Section 117960, when any of the information the plan changes and shall have the plan on file for review during an inspection or upon request. The updated plan shall be submitted within 30 days of the change.

117971 – Inspection and Enforcement Cost Recovery

In addition to the fees collected pursuant to Section 117995, the department, in the implementation of this part, shall recover its actual costs for services related to large quantity medical waste generator follow up inspections and enforcement activities necessary to ensure compliance with this part. In no event shall the department charge more than the actual costs incurred by the department.

117975 - Treatment and tracking Records

(a) A large quantity medical waste generator required to register pursuant to this chapter shall maintain for a minimum of two years individual treatment and shipping and tracking documents for all untreated medical waste shipped offsite for treatment. The generator shall report or submit to the enforcement agency, upon request, all of the following:

(1) Treatment operating records. Operating records shall be maintained in written or electronic form.

(2) An emergency action plan in accordance with regulations adopted by the department.

(3) Shipping and tracking documents or electronically archived shipping and tracking documents maintained by the facility or medical waste hauler of all untreated medical waste shipped offsite for treatment.

(b) Documentation shall be made available to the enforcement agency onsite as soon as feasible, but no more than two business days following the request.

117976- Materials of Trade Exemption

(a) A large quantity medical waste generator or parent organization that employs health care professionals who generate medical waste may transport medical waste generated in limited quantities up to 35.2 pounds to the central location of accumulation, provided that all of the following are met:

(1) The principal business of the generator is not to transport or treat regulated medical waste.

(2) The generator shall adhere to the conditions and requirements set forth in the materials of trade exception, as specified in Section 173.6 of Title 49 of the Code of Federal Regulations.

(3) A person transporting medical waste pursuant to this section shall provide a form or log to the receiving facility, and the receiving facility shall maintain the form or log for a period of two years, containing all of the following information:

(A) The name of the person transporting the medical waste.

(B) The number of containers of medical waste transported.

(C) The date the medical waste was transported.

(b) A generator transporting medical waste pursuant to this section shall not be regulated as a hazardous waste hauler pursuant to Section 117660.

117980 - Containment and Storage

Containment and storage of medical waste shall be in accordance with Chapter 9 (commencing with Section 118275).

117985 - Treatment

Medical waste shall be treated using treatment technologies approved in accordance with Chapter 8 (commencing with Section 118215).

117990 - Fees

The fee schedule specified in Section 117995 shall be for the issuance of medical waste registrations and onsite medical waste treatment facility permits when the department serves as the enforcement agency for large quantity generators. This fee schedule shall be adjusted annually in accordance with Section 100425, or as provided in the regulations adopted by the department, not to exceed the reasonable regulatory costs of the department. Local enforcement agencies shall set fees that shall be sufficient to cover their costs in implementing this part with regard to large quantity generators.

117995 - Collect Fees

The registration and annual permit fee for large quantity generators shall be set in following amounts:

(a)

(1) A general acute care hospital, as defined in subdivision (a) of Section 1250, that has one or more beds, but not more than 99 beds, shall pay six hundred dollars (\$600), a facility with 100 or more beds, but not more than 199 beds, shall pay eight hundred sixty dollars (\$860), a facility with 200 or more beds, but not more than 250 beds shall pay one thousand one hundred dollars (\$1,100), and a facility with 251 or more beds shall pay one thousand four hundred dollars (\$1,400).

(2) In addition to the fees specified in paragraph (1), a general acute care hospital which is providing onsite treatment of medical waste shall pay an annual medical waste treatment facility inspection and permit fee of three hundred dollars (\$300), if the facility has one or more beds but not more than 99 beds, five hundred dollars (\$500), if the facility has 100 or more beds but not more than 250 beds, and one thousand dollars (\$1,000), if the facility has 251 or more beds.

(b) A specialty clinic, providing surgical, dialysis, or rehabilitation services, as defined in subdivision (b) of Section 1204, shall pay three hundred fifty dollars (\$350).

(c) A skilled nursing facility, as defined in subdivision (c) of Section 1250, that has one or more beds, but not more than 99 beds shall pay two hundred seventy-five dollars (\$275), a facility with 100 or more beds, but not more than 199 beds shall pay three hundred fifty dollars (\$350), and a facility with 200 or more beds shall pay four hundred dollars (\$400).

(d) An acute psychiatric hospital, as defined in subdivision (b) of Section 1250, shall pay two hundred dollars (\$200).

- (e) An intermediate care facility, as defined in subdivision (d) of Section 1250, shall pay three hundred dollars (\$300).
- (f) A primary care clinic, as defined in Section 1200.1, shall pay three hundred fifty dollars (\$350).
- (g) A licensed clinical laboratory, as defined in paragraph (3) of subdivision (a) of Section 1206 of the Business and Professions Code, shall pay two hundred dollars (\$200).
- (h) A health care service plan facility, as defined in subdivision (f) of Section 1345, shall pay three hundred fifty dollars (\$350).
- (i) A veterinary clinic or veterinary hospital shall pay two hundred dollars (\$200).
- (j) A large quantity generator medical office shall pay two hundred dollars (\$200).
- (k) In addition to the fees specified in subdivisions (b) to (j), inclusive, a large quantity generator of medical waste which is providing onsite treatment of medical waste shall pay an annual medical waste treatment facility inspection and permit fee of three hundred dollars (\$300).
- (l) The department may collect annual fees and issue permits on a biennial basis.

Chapter 6 - Medical Waste Haulers

118000 - Transportation of Medical Waste

- (a) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal.
- (b) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.
- (c) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being shipped out of the state.

118025 - Registration

All medical waste shall be hauled by a registered hazardous waste hauler, the United States Postal Service, or by a person with an exemption granted pursuant to Section 117946 for small quantity generators or pursuant to Section 117976 for large quantity generators.

118027 - Unknowingly Transports

A person who is authorized to collect solid waste, as defined in Section 40191 of the Public Resources Code, who unknowingly transports medical waste to a solid waste facility, as defined in Section 40194 of the Public Resources Code, incidental to the collection of solid waste, is exempt from the provisions of the Medical Waste Management Act with regard to that waste. If a solid waste transporter discovers that he or she has hauled untreated medical waste to a landfill or materials recovery facility, he or she shall contact the originating generator of the medical waste to respond to the landfill or recovery facility to provide ultimate proper disposal of the medical waste. The solid waste facility operator may, at its discretion and after contacting the generator, make arrangements for the proper treatment and disposal of the medical waste at a facility approved by the department. Title to the waste remains with the generator. Reimbursement costs for the proper management of discovered waste shall be the originating generator's responsibility.

118029 - Information Requirements

(a) Haulers of medical waste in California, with the exception of those using a materials of trade exception as specified in Sections 117946 and 117976, and United States Department of Transportation licensed common carriers hauling pharmaceutical waste, shall meet all United States Department of Transportation requirements for transporting medical waste and shall be hazardous waste haulers in California. On or before July 1 of each year, a registered hazardous waste hauler that transports medical waste shall so notify the department, and provide, in a format that conforms to the protocol requirements for submission of data to the department, the following information:

(1) Business name, address, and telephone number.

(2) Name of owner, operator, and contact person.

(3) Hazardous waste transporter registration number.

(4) The number of vehicles and trailers transporting medical waste within the state as of that date.

(5) Types and quantities of medical waste collected, in pounds.

(6) The names of the generators whose waste has been transported by the hauler and the amounts of medical waste transported, by waste type category.

(b) Each registered hazardous waste hauler shall provide to the department a list of all medical waste generators serviced by that person during the previous 12 months. That list shall include the business name, business address, mailing address, telephone number, and other information as required by the department to collect annual fees pursuant to Section 117924. The list shall be provided to the department within 10 days of the close of the earliest calendar quarter ending September 30, December 31, March 31, or June 30, or as otherwise required by the department.

118032 - Pharmaceutical Waste Hauling Exemption

A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

(a) The generator or parent organization has on file one of the following:

(1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117925), a medical waste management plan prepared pursuant to Section 117935.

(2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117925), the information document maintained pursuant to subdivision (a) of Section 117945.

(3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the shipping and tracking documents, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the shipping and tracking documents, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies between the items received and the shipping and tracking documents, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the shipping and tracking documents, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the

purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

- (A) The name of the person transporting the pharmaceutical waste.
 - (B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate pharmaceutical waste container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.
 - (C) The date that the pharmaceutical waste was returned.
- (2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the pharmaceutical waste.
- (3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

118033 – Secure Pharmaceutical Waste

The pharmaceutical waste that is separated from medical waste by the generator shall be maintained in a manner to secure the pharmaceutical waste contents from access by unauthorized individuals. Any suspected or confirmed tampering of, unauthorized access to, or loss of this pharmaceutical waste shall be reported to the appropriate state licensing authority.

118035 - Transfer of Medical Waste

For the purpose of transferring medical waste prior to reaching a permitted medical waste treatment facility, medical waste shall not be unloaded, reloaded, or transferred to another vehicle at any location, except at a permitted medical waste transfer station or in the case of a vehicle breakdown or other emergency.

118040 - Tracking Records

- (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed shipping document in compliance with United States Department of Transportation (USDOT) requirements when medical waste is transported. In addition to the shipping document required by USDOT, a hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical

waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the shipping and tracking documents for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the shipping and tracking documents for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

- (1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.
- (2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.
- (3) The name, address, and telephone number of the generator.
- (4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.
- (5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have the shipping and tracking documents in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original shipping and tracking documents.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

118045 - Transfer Station Permit

(a) The department shall charge an application fee for a permit for a transfer station equal to one hundred dollars (\$100) for each hour which the department spends on processing the application, but not more than ten thousand dollars (\$10,000), or as provided in the regulations adopted by the department, not to exceed the reasonable regulatory costs of the department.

(b) In addition to the fee specified in subdivision (a), the annual permit fee for a transfer is two thousand dollars (\$2,000), or as provided in the regulations adopted pursuant to this part, not to exceed the reasonable regulatory costs of the department.

Chapter 7 - Medical Waste Treatment Facility Permits

118130 - Permits

All offsite medical waste treatment facilities and transfer stations shall be permitted and inspected by the department. All onsite medical waste treatment facilities shall be permitted and inspected by the enforcement agency.

118135 - Permit Dates

Each person operating an offsite medical waste treatment facility shall obtain a permit pursuant to this chapter from the department prior to commencement of the treatment facility's operation.

118140 - Accepting Medical Waste

A health care facility accepting medical waste for treatment from the physicians and surgeons who are on the staff of the facility and who are small quantity generators shall be classified as an onsite treatment facility and shall be permitted and inspected by the enforcement agency.

118145 - Adjacent Small Quantity Generators

A health care facility accepting medical waste for treatment from small quantity generators that are adjacent to the facility shall be classified as an onsite treatment facility and shall be permitted and inspected by the enforcement agency.

118147 - Consolidation

Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

- (a) The generator of the sharps waste, a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste to the medical waste generator's facility.
- (b) The sharps waste is accepted at a central location at the medical waste generator's facility.
- (c) A reference to, and a description of, the actions taken pursuant to this section are included in the facility's medical waste management plan adopted pursuant to Section 117960.

118150 - Compliance

Each enforcement agency shall follow procedures that are consistent with the Medical Waste Management Act and the regulations adopted pursuant to this chapter, when issuing medical waste permits.

118155 - Permits

A person required to obtain an offsite medical waste treatment facility permit pursuant to this part shall file with the enforcement agency an application containing, but not limited to, all of the following:

- (a) The name of the applicant.
- (b) The business address of the applicant.
- (c) The type of treatment provided, the treatment capacity of the facility, a characterization of the waste treated at this facility, and the estimated average monthly quantity of waste treated at the facility.
- (d) A disclosure statement, as provided in Section 25112.5, except for onsite medical waste treatment facilities.
- (e) A plan for closure of the facility using, at minimum, one of the methods of decontamination specified in subdivision (a) or (b) of Section 118295, thereby rendering the property to an acceptable sanitary condition following the ending of treatment services at the site.
- (f) Any other information required by the enforcement agency for the administration or enforcement of this part or the regulations adopted pursuant to this part.

118160 - Permit Requirements

- (a) Prior to issuing or renewing a permit for an offsite medical waste treatment facility, the department shall review the compliance history of the applicant, under any local, state, or federal law or regulation governing the control of medical waste or pollution.
- (b) The department shall, pursuant to this section, deny a permit, or specify additional permit conditions, to ensure compliance with applicable regulations, if the department determines that in the three-year period preceding the date of application the applicant has violated laws or regulations identified in subdivision (a) at a facility owned or operated by the applicant, and the violations demonstrate a recurring pattern of noncompliance or pose, or have posed, a significant risk to public health and safety or to the environment.
- (c) In making the determination of whether to deny a permit or to specify additional permit conditions, the department shall take both of the following into consideration:
 - (1) Whether a permit denial or permit condition is appropriate or necessary given the severity of the violation.
 - (2) Whether the violation has been corrected in a timely fashion.

118165 - Treatment Records

On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

- (a) The type of treatment facility and its capacity.
- (b) All treatment facility operating records.
- (c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators, hazardous waste haulers, or, pursuant to Section 118032, common carriers.

118170 - Duration of Permit

- (a) A medical waste permit issued by the enforcement agency to a medical waste treatment facility shall be valid for five years.
- (b) An application for renewal of the permit shall be filed with the enforcement agency not less than 90 days prior to the expiration date. If a permittee fails to make a timely application for renewal, the medical waste permit shall expire on the expiration date.

118175 - Conditions for Granting Permit

- (a) A medical waste permit may be renewed if the enforcement agency finds the permittee has been in substantial compliance with this part and the regulations adopted pursuant to this part during the preceding permitted period or that the permittee corrected previous violations in a timely manner.
- (b) Upon approval of the enforcement agency, a permit may be transferred from one subsidiary to another subsidiary of the same corporation, from a parent corporation to one of its subsidiaries, or from a subsidiary to a parent corporation.

118180 - Permit Validity

A person required to obtain a medical waste permit shall, at all times, possess a valid permit for each facility in operation. A medical waste permit shall terminate prior to its expiration date if suspended or revoked pursuant to Section 118350 or, notwithstanding Section 118355, if either of the following occurs:

- (a) The permittee sells or otherwise transfers the facility, except as specified in subdivision (b) of Section 118175.
- (b) The permittee surrenders the permit to the enforcement agency because the permittee ceases operation.

118185 - Permit Procedures

The enforcement agency shall issue a medical waste permit upon evaluation, inspection, or records review of the applicant if the applicant is in substantial compliance with this part and the

regulations adopted pursuant to this part and the applicant has corrected any previous violations. A decision to issue or not to issue the permit shall be made by the enforcement agency within 180 days of the time that the application is deemed complete, unless waived by the applicant.

118190 - Permit Conditions

When issuing, renewing, or revising any treatment facility permit, the enforcement agency may prohibit or condition the handling or treatment of medical waste to protect the public health and safety.

118195 - Denial of Permit

An enforcement agency shall inform an applicant for a medical waste permit, in writing, upon the denial of any application for the permit. Within 20 days after the enforcement agency mails the notice, the applicant may present a written petition for a hearing to the enforcement agency. Upon receipt by the enforcement agency of the petition in proper form, the petition shall be set for hearing.

If the department is the enforcement agency, the proceedings shall commence with the filing of a statement of issues and shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department has all the powers granted to a department in that chapter.

If the department is not the enforcement agency, the hearings shall be held in accordance with the ordinance adopting the medical waste management program.

118200 - Inspection

The enforcement agency shall evaluate, inspect, and review the records of medical waste treatment facilities for compliance with this part.

118205 - Fees

The fee schedule specified in Section 118210 shall cover the issuance of medical waste treatment facility permits and an inspection program, when the department serves as the enforcement agency. This fee schedule shall be adjusted annually in accordance with Section 100425. The department may adjust by regulation the fees specified in Section 118210 to reflect the actual costs of implementing this chapter. Local enforcement agencies shall set fees that shall be sufficient to cover their costs in implementing this part with regard to large quantity generators.

118210 – Collect Fees

(a) The department shall charge an annual permit fee for an offsite medical waste treatment facility equal to either one hundred twenty-seven ten thousandths of a cent (\$0.0127) for each pound of medical waste treated or twelve thousand dollars (\$12,000), whichever is greater. The department may collect annual fees and issue permits on a biennial basis.

(b) The department shall charge an initial application fee for each type of treatment technology at an offsite medical waste treatment facility equal to one hundred dollars (\$100) for each hour the department spends processing the application, but not more than fifty thousand dollars (\$50,000), or as provided in the regulations adopted by the department.

Chapter 8 - Treatment

118215 - Methods

(a) Except as provided in subdivisions (b) and (c), a person generating or treating medical waste shall ensure that the medical waste is treated by one of the following methods, thereby rendering it solid waste, as defined in Section 40191 of the Public Resources Code, prior to disposal:

(1)

(A) Incineration at a permitted medical waste treatment facility in a controlled-air, multi-chamber incinerator, or other method of incineration approved by the department which provides complete combustion of the waste into carbonized or mineralized ash.

(B) Treatment with an alternative technology approved pursuant to paragraph (3), which, due to the extremely high temperatures of treatment in excess of 1300 degrees Fahrenheit, has received express approval from the department.

(2) Steam sterilization at a permitted medical waste treatment facility or by other sterilization, in accordance with all of the following operating procedures for steam sterilizers or other sterilization:

(A) Standard written operating procedures shall be established for biological indicators, or for other indicators of adequate sterilization approved by the department, for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity.

(B) Recording or indicating thermometers shall be checked during each complete cycle to ensure the attainment of 121* Centigrade (250* Fahrenheit) for at least one-half hour, depending on the quantity and density of the load, to achieve sterilization of the entire load. Thermometers, thermocouples, or other monitoring devices identified in the facility operating plan shall be checked for calibration annually. Records of the calibration checks shall be maintained as part of the facility's files and records for a period of two years or for the period specified in the regulations.

(C) Heat-sensitive tape, or another method acceptable to the enforcement agency, shall be used on each biohazard bag or sharps container that is processed onsite to indicate that the waste went through heat treatment. If the

biohazard bags or sharps containers are placed in a large liner bag within the autoclave for treatment, heat-sensitive tape or another method acceptable to the enforcement agency only needs to be placed on the liner bag and not on every hazardous waste bag or sharps container being treated.

(D) The biological indicator *Geobacillus stearothermophilus*, or other indicator of adequate sterilization as approved by the department, shall be placed at the center of a load processed under standard operating conditions at least monthly to confirm the attainment of adequate sterilization conditions.

(E) Records of the procedures specified in subparagraphs (A), (B), and (D) shall be maintained for a period of not less than two years.

(3)

(A) Other alternative medical waste treatment methods which are both of the following:

(i) Approved by the department.

(ii) Result in the destruction of pathogenic micro-organisms.

(B) Any alternative medical waste treatment method proposed to the department shall be evaluated by the department and either approved or rejected pursuant to the criteria specified in this subdivision.

(b) Fluid blood or blood products may be discharged to a public sewage system without treatment if its discharge is consistent with waste discharge requirements placed on the public sewage system by the California regional water quality control board with jurisdiction.

(c)

(1) A medical waste that is a biohazardous laboratory waste, as defined in subparagraph (B) of paragraph (1) of subdivision (b) of Section 117690, may be treated by a chemical disinfection if the waste is liquid or semi-liquid and the chemical disinfection method is recognized by the National Institutes of Health, the Centers for Disease Control and Prevention, or the American Biological Safety Association, and if the use of chemical disinfection as a treatment method is identified in the site's medical waste management plan.

(2) If the waste is not treated by chemical disinfection, in accordance with paragraph (1), the waste shall be treated by one of the methods specified in subdivision (a).

(3) Following treatment by chemical disinfection, the medical waste may be discharged to the public sewage system if the discharge is consistent with waste discharge requirements placed on the public sewage system by the California regional water control board, and the discharge is in compliance with the

requirements imposed by the owner or operator of the public sewage system. If the chemical disinfection of the medical waste causes the waste to become a hazardous waste, the waste shall be managed in accordance with the requirements of Chapter 6.5 (commencing with Section 25100) of Division 20.

118220 - Anatomical Parts

Pathology waste of a human nature, as defined in subparagraph (A) of paragraph (2) of subdivision (b) of Section 117690, shall be disposed of by interment, incineration, or alternative treatment technologies approved to treat this type of waste, pursuant to paragraph (1) or paragraph (3) of subdivision (a) of Section 118215.

118222 - Waste Requiring Specified Methods

(a) Pathology waste that meets the conditions of paragraph (2) of subdivision (b) of Section 117690 and trace chemotherapy waste that meets the conditions of paragraph (5) of subdivision (b) of Section 117690 shall be treated by incineration or alternative treatment technologies approved to treat that waste pursuant to paragraph (1) or paragraph (3) of subdivision (a) of Section 118215 prior to disposal.

(b) Pharmaceutical waste from health care settings that meets the conditions specified in paragraph (3) of subdivision (b) of Section 117690 shall be treated by incineration or alternative treatment technologies approved to treat that waste pursuant to paragraph (1) or paragraph (3) of subdivision (a) of Section 118215 prior to disposal.

118225 - Sharps Waste

(a) Sharps waste shall be rendered noninfectious prior to disposal by one of the following methods:

(1) Incineration.

(2) Steam sterilization.

(3) Disinfection using an alternative treatment method approved by the department.

(b) Sharps waste rendered noninfectious pursuant to this section may be disposed of as solid waste if the waste is not otherwise hazardous.

(c) Onsite medical waste treatment facilities treating sharps waste pursuant to paragraph (2) or (3) of subdivision (a) shall ensure that, prior to disposal, the treated sharps waste is destroyed or that public access to the treated sharps waste is prevented.

118230 - Incineration

An operator of a hazardous waste incinerator permitted pursuant to Section 25200 may also accept medical waste for incineration.

118235 - Emergency Action Plan

Each medical waste treatment facility issued a medical waste permit shall provide the enforcement agency with an emergency action plan that the facility shall follow to ensure the proper disposal of medical waste in the event of equipment breakdowns, natural disasters, or other occurrences.

118240 - Animal Carcasses

Notwithstanding Section 9141 of the Food and Agricultural Code, animals that die from infectious diseases or that are euthanized because they are suspected of having been exposed to infectious disease shall be treated with a treatment technology approved by the department for that use if, in the opinion of the attending veterinarian or local health officer, the carcass presents a danger of infection to humans.

118245 - Fees for Alternative Treatment Technologies and Mail-Back Systems

The department shall charge an application fee for evaluation of an alternative treatment technology of two thousand five hundred dollars (\$2,500) and shall charge an additional fee equal to one hundred dollars (\$100) per hour for each hour which the department spends on processing the application, but not more than a total of five thousand dollars (\$5,000), or as provided in the regulations adopted by the department, not to exceed the reasonable regulatory costs of the department.

Chapter 9 - Containment and Storage

118275 - Medical Waste Segregation and Storage

(a) To containerize or store medical waste at the point of generation and while collected in that room, a person shall do all of the following:

(1) Medical waste, as defined in Section 117690, shall be contained separately from other waste at the point of origin in the producing facility. Sharps containers may be placed in biohazard bags or in containers with biohazard bags.

(2) Biohazardous waste, as defined in paragraph (1) of subdivision (b) of Section 117690, shall be placed in a biohazard bag conspicuously labeled with the words "Biohazardous Waste" or with the international biohazard symbol and the word "BIOHAZARD."

(3) Sharps waste, as defined in paragraph (4) of subdivision (b) of Section 117690, including sharps and pharmaceutical waste containerized pursuant to paragraph (7), shall be contained in a United States Food and Drug Administration (USFDA) approved sharps container that meets USFDA labeling requirements and is handled pursuant to Section 118285.

(4) Trace chemotherapy waste, as defined in paragraph (5) of subdivision (b) of Section 117690, shall be segregated for storage, and, when placed in a secondary container, that container shall be labeled with the words "Chemotherapy Waste", "CHEMO", or other label approved by the department on the lid and sides, so as to be visible from

any lateral direction, to ensure treatment of the biohazardous waste pursuant to Section 118222. Sharps waste that is contaminated through contact with, or having previously contained, chemotherapeutic agents, shall be placed in sharps containers labeled in accordance with the industry standard with the words "Chemotherapy Waste," "Chemo," or other label approved by the department, and shall be segregated to ensure treatment of the sharps waste pursuant to Section 118222.

(5) Pathology waste, as defined in paragraph (2) of subdivision (b) of Section 117690, shall be segregated for storage and, when placed in a secondary container, that container shall be labeled with the words "Pathology Waste", " PATH", or other label approved by the department on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the waste pursuant to Section 118222.

(6) Pharmaceutical waste, as defined in paragraph (3) of subdivision (b) of Section 117690, shall be segregated for storage in accordance with the facility's medical waste management plan. When this waste is prepared for shipment offsite for treatment, it shall be properly containerized for shipment in compliance with United States Department of Transportation and United States Drug Enforcement Agency (DEA) requirements.

(A) Pharmaceutical wastes classified by the DEA as "controlled substances" shall be disposed of in compliance with DEA requirements.

(B) Nonradioactive pharmaceutical wastes that are not subject to the federal Resource Conservation and Recovery Act of 1976 (Public Law 94-580), as amended, and that are regulated as medical waste are placed in a container or secondary container labeled with the words "HIGH HEAT OR INCINERATION ONLY," or with another label approved by the department, on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the biohazardous waste pursuant to Section 118222.

(7) A person may consolidate into a common container, which may be reusable, sharps waste, as defined in paragraph (4) of subdivision (b) of Section 117690, and pharmaceutical wastes, as defined in paragraph (3) of subdivision (b) of Section 117690, provided that both of the following apply:

(A) The consolidated waste is treated by incineration or alternative treatment technologies approved to treat that waste pursuant to paragraph (1) or (3) of subdivision (a) of Section 118215 prior to disposal. That alternative treatment shall render the waste unrecoverable and nonhazardous.

(B) The container meets the requirements of Section 118285. The container shall be labeled with the biohazardous waste symbol and the words "HIGH HEAT OR INCINERATION ONLY," or with another label approved by the department, on the lid and sides, so as to be visible from any lateral direction, to ensure treatment of the waste pursuant to this subdivision.

(b) To containerize medical waste being held for shipment offsite for treatment, the waste shall be labeled, as outlined in subdivision (a), on the lid and sides of the container.

(c) When medical waste is containerized pursuant to subdivisions (a) and (b) there is no requirement to label the containers with the date that the waste started to accumulate.

118280 - Containment and Storage

To containerize biohazard bags, a person shall do all of the following:

(a) The bags shall be tied to prevent leakage or expulsion of contents during all future storage and handling. When containers are prepared for transport offsite from the facility, they shall be prepared in compliance with United States Department of Transportation requirements.

(b) (1) Medical waste may be placed into a biohazard bag not to exceed three pounds or one gallon and tied, as required in subdivision (a), in a patient room and shall be immediately transported upon completion of the procedure directly from the point of generation and placed into a biohazard container stored in a soiled utility room or other biohazardous waste storage without having first been placed into a secondary container in the patient room.

(2) Medical waste may be placed into a biohazard bag hung on a hamper stand in a surgery suite and the bag removed from the hamper stand after completion of the procedure, taken out of the surgery suite, and placed into a biohazard container stored in a soiled utility room or other biohazard waste storage area.

(c) Biohazardous waste, except as provided in subdivision (b), shall be bagged in accordance with subdivision (b) of Section 118275 and placed for storage, handling, or transport in a rigid container which may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be recycled with the approval of the enforcement agency. Containers may be of any color and shall be labeled with the words "Biohazardous Waste" or with the international biohazard symbol and the word "BIOHAZARD" on the lid and on the sides so as to be visible from any lateral direction. Containers shall comply with United States Department of Transportation requirements when prepared for transport offsite from the facility.

(d) Biohazardous waste shall not be removed from the biohazard bag until treatment as prescribed in Chapter 8 (commencing with Section 118215) is completed, except to eliminate a safety hazard, or by the enforcement officer in performance of an investigation pursuant to Section 117820. Biohazardous waste shall not be disposed of before being treated as prescribed in Chapter 8 (commencing with Section 118215).

(e) (1) Except as provided in paragraph (5), a person generating biohazardous waste shall comply with the following requirements:

(A) If the person generates 20 or more pounds of biohazardous waste per month, the person shall not contain or store that waste above 0° Centigrade (32° Fahrenheit) at an onsite location for more than seven days without obtaining prior written approval of the enforcement agency.

(B) If a person generates less than 20 pounds of biohazardous waste per month, the person shall not contain or store that waste above 0° Centigrade (32° Fahrenheit) at an onsite location for more than 30 days.

(2) A person may store biohazardous waste at or below 0° Centigrade (32° Fahrenheit) at an onsite location for not more than 90 days without obtaining prior written approval of the enforcement agency.

(3) A person may store biohazardous waste at a permitted transfer station at or below 0° Centigrade (32° Fahrenheit) for not more than 30 days without obtaining prior written approval of the enforcement agency.

(4) A person shall not store biohazardous waste above 0° Centigrade (32° Fahrenheit) at a location or facility which is offsite from the generator for more than seven days before treatment.

(5) Notwithstanding paragraphs (1) to (4), inclusive, if the odor from biohazardous or sharps waste stored at a facility poses a nuisance, the enforcement agency may require more frequent removal.

(f) Waste that meets the definition of pharmaceutical waste in paragraph (3) of subdivision (b) of Section 117690 shall not be subject to the limitations on storage time prescribed in subdivision (e). A person may store that pharmaceutical waste at an onsite location for not longer than 90 days when the container is ready for disposal or, unless prior written approval from the enforcement agency is obtained. The container shall be emptied at least once a year unless prior written approval from the enforcement agency is obtained. A person may store that pharmaceutical waste at a permitted transfer station for not longer than 30 days without obtaining prior written approval from the enforcement agency. A person shall not store that pharmaceutical waste at any location or facility that is offsite from the generator for more than 30 days before treatment.

(g) The containment and storage time for wastes consolidated in a common container pursuant to paragraph (7) of subdivision (a) of Section 118275 shall not exceed the storage time for any category of waste set forth in this section.

118285 - Sharps Waste

To containerize sharps waste, a person shall do all of the following:

(a) Place all sharps waste into a sharps container.

(b) Tape closed or tightly lid full sharps containers ready for disposal to preclude loss of contents.

(c) Store sharps containers ready for disposal for not more than thirty days without the written approval of the enforcement agency.

(d) Label sharps containers with the words "sharps waste" or with the international biohazard symbol and the word "BIOHAZARD".

118286 – Management of Home-generated Sharps Waste

(a) A person shall not knowingly place home-generated sharps waste in any of the following containers:

(1) Any container used for the collection of solid waste, recyclable materials, or greenwaste.

(2) Any container used for the commercial collection of solid waste or recyclable materials from business establishments.

(3) Any roll-off container used for the collection of solid waste, construction, and demolition debris, greenwaste, or other recyclable materials.

(b) Home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:

(1) A household hazardous waste facility pursuant to Section 25218.13.

(2) A "home-generated sharps consolidation point" as defined in subdivision (b) of Section 117904.

(3) A medical waste generator's facility pursuant to Section 118147.

(4) A facility through the use of a medical waste mail-back container approved by the United States Postal Service.

118290 - Common Storage Facility

Any small quantity generator who has properly containerized the medical waste according to the requirements of this article may store the waste in a permitted common storage facility.

118295 - Wash and Decontaminate Containers

A person shall thoroughly wash and decontaminate reusable rigid containers for medical waste by a method approved by the enforcement agency each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners, bags, or other devices removed with the waste. These containers shall be maintained in

a clean and sanitary manner. Approved methods of decontamination include, but are not limited to, agitation to remove visible soil combined with one of the following procedures:

- (a) Exposure to hot water of at least 82° Centigrade (180° Fahrenheit) for a minimum of 15 seconds.
- (b) Exposure to chemical sanitizer by rinsing with, or immersion in, one of the following for a minimum of three minutes:
 - (1) Hypochlorite solution (500 ppm available chlorine).
 - (2) Phenolic solution (500 ppm active agent).
 - (3) Iodoform solution (100 ppm available iodine).
 - (4) Quaternary ammonium solution (400 ppm active agent).

118300 - Spill Decontamination

Any leak or spill of a medical waste by a medical waste generator, hazardous waste hauler, or treatment facility shall be decontaminated by procedures adopted by the department.

118305 - Solid Waste

A person shall not use reusable pails, drums, dumpsters, or bins used for medical waste for the containment of solid waste, or for other purposes, except after being decontaminated by the procedures specified in Section 118295 and removal of all medical waste labels.

118307 – Interim Storage Area

Medical waste that is stored in an area prior to transfer to the designated accumulation area, as defined in Section 118310, shall be stored in an area that is either locked or under direction supervision or surveillance. Intermediate storage areas shall be marked with the international biohazard symbol or the signage described in Section 118310. These warning signs shall be readily legible from a distance of five feet. This section does not apply to the rooms in which medical waste is generated.

118310 – Designated Accumulation Area

A designated accumulation area used for the storage of medical waste containers prior to transportation or treatment shall be secured so as to deny access to unauthorized persons and shall be marked with warning signs on, or adjacent to, the exterior of entry doors, gates, or lids. The storage area may be secured by use of locks on entry doors, gates, or receptacle lids.

The wording of warning signs shall be in English, "CAUTION—BIOHAZARDOUS WASTE STORAGE AREA—UNAUTHORIZED PERSONS KEEP OUT," and in Spanish, "CUIDADO—ZONA DE RESIDUOS—BIOLÓGICOS PELIGROSOS—PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS," or in another language, in addition to English, determined to be appropriate by the infection control staff or enforcement agency. A warning sign concerning infectious waste, as that term was defined by Section 25117.5 as it read on December 31, 1990,

that sign having been installed before April 1, 1991, meets the requirements of this section, until the sign is changed and as long as the sign is not moved. Warning signs shall be readily legible during daylight from a distance of at least 25 feet.

Any enclosure or designated accumulation area shall provide medical waste protection from animals and natural elements and shall not provide a breeding place or a food source for insects or rodents.

118315 - Trash Chutes

A person shall not use a trash chute to transfer medical waste.

118320 - Compactors or Grinders

(a) Except as provided in subdivision (b), compactors or grinders shall not be used to process medical waste until after the waste has been treated pursuant to Chapter 8 (commencing with Section 118215) and rendered solid waste.

(b)

(1) Grinding or compacting may be used when it is an integral part of an alternative treatment method approved by the department.

(2) A compactor may be used to compact medical waste if the type of medical waste compactor proposed to be used is evaluated by the department, and approved by the department prior to its use pursuant to the following criteria:

(A) The compactor operates without the release of liquids or pathogenic microorganisms from the medical waste during placement of the medical waste into, or removal of the medical waste from, the compactor units, and during the compaction process.

(B) The compacted medical waste will not release liquids or pathogens during any sub-subsequent handling and no residual waste will be left in the compactor unit after the process is completed.

(C) Compactor operations and maintenance personnel will not be at any substantial increased risk of exposure to pathogens.

(D) The compactor has been demonstrated not to have any adverse effects on any treatment method. If only specific treatment methods are compatible with the compaction process, the department shall condition its approval of the compactor for use only in conjunction with treatment methods, with regard to which no adverse effects have been demonstrated.

(c) Medical waste in bags or other containers shall not be subject to compaction by any compacting device and shall not be placed for storage or transport in a portable or mobile trash compactor, except as allowed pursuant to subdivision (b).

Chapter 9.5 - Trauma Scene Waste Management

118321 - Citation of Part

(a) This chapter shall be known, and may be cited, as the Trauma Scene Waste Management Act.

(b) The Legislature hereby finds and declares that it is in the interests of the health and safety of the public and the solid waste industry to regulate the handling and treatment of waste that, but for contamination with large quantities of human blood or body fluids as a result of death, serious injury, or illness, would be solid waste.

(c) The Legislature further finds and declares that, in the interest of safe and uniform management of trauma scene waste, practitioners of trauma scene management should be subject to regulation by the department.

118321.1 - Registration and Fees

(a) A trauma scene waste management practitioner shall register with the department on forms provided by the department.

(b) The department shall register a trauma scene waste management practitioner and issue a trauma scene waste hauling permit to a trauma scene waste management practitioner who submits a completed application form and the registration fee, upon approval of the application by the department.

(c) A registered trauma scene waste management practitioner is exempt from the registration requirements imposed pursuant to Chapter 6 (commencing with Section 118025) or Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20 upon haulers of medical waste.

(d) Registered trauma scene waste management practitioners shall pay an annual fee of two hundred dollars (\$200) to the department for deposit in the fund. The fee revenues deposited in the fund pursuant to this subdivision may be expended by the department, upon appropriation by the Legislature, for the implementation of this chapter.

118321.2 - List of Practitioners

(a) The department shall maintain an inventory of registered trauma scene waste management practitioners.

(b) The department shall submit a list of registered trauma scene waste management practitioners to all local agency health officers and directors of environmental health, county administrators, and county sheriffs, and shall make the list available, upon request, to other public agencies and to the public.

118321.3 - Department Duties

(a) Notwithstanding Section 117650, the department shall be the sole enforcement agency with regard to the management of trauma scene waste.

(b) The department, working with the trauma scene waste management industry and the health care industry, shall establish the following standards:

(1) Documentation of personal protection required to be provided for, and used by, workers in accordance with the California Occupational and Safety Administration's bloodborne pathogen standards.

(2) Technologies and chemicals appropriate to the task of cleanup and disinfecting.

(c) The department may adopt regulations pursuant to which trauma scene waste management practitioners shall document both of the following:

(1) Identification of trauma scene waste within the scope of this chapter.

(2) Compliance with disposal requirements, including, but not limited to, tracking the transportation of trauma scene waste.

(d) The department shall adopt procedures to provide information to trauma scene waste management practitioners recommending procedures for removing trauma scene waste from trauma scenes.

118321.4 - Transporter Deemed Generator

As specified in Section 117705, a trauma scene waste management practitioner who transports trauma scene waste shall be deemed the generator of the trauma scene waste for purposes of this part.

118321.5 - Removal, Transportation, and Storage

(a) Trauma scene waste shall be removed from the trauma scene immediately upon completion of the removal phase of a trauma scene waste removal operation.

(b) Trauma scene waste shall be transported to a permitted medical waste transfer station or treatment facility pursuant to subdivision (a) of Section 118000, or may be stored in a dedicated freezer at the business location of the trauma scene waste management practitioner for a period of not more than 14 days, or as otherwise approved by the department.

118321.6 - Limitations

(a) This chapter does not limit or abridge the jurisdiction of the Division of Occupational Safety and Health of the Department of Industrial Relations.

(b) This chapter does not prohibit a business from employing or contracting with a person to provide cleanup or consultative services, including those services provided by an industrial hygienist, with respect to trauma scene waste if those services are incidental to the principal course and scope of services provided by the person.

Chapter 10 - Enforcement

118325 - Injunction for Violations

An enforcement agency, district attorney, city attorney, or city prosecutor may bring an action to enjoin the violation, or threatened violation, of this part or the regulations adopted pursuant to this part, in the superior court in the county where the violation occurred or is about to occur. Any proceeding under this section shall be in accordance with Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the enforcement agency, district attorney, city attorney, or city prosecutor is not required to allege facts necessary to show or tending to show the lack of an adequate remedy at law or irreparable damage or loss. With respect to any action brought pursuant to this section alleging actual violation of this part or the regulations adopted pursuant to this part, the court shall, if it finds the allegations to be true, issue its order enjoining the continuance of the violation.

118330 - Order for Compliance / Administrative Penalty

Whenever the enforcement agency determines that a violation or threatened violation of this part or the regulations adopted pursuant to this part has resulted, or is likely to result, in a release of medical waste into the environment, the agency may issue an order to the responsible person specifying a schedule for compliance or imposing an administrative penalty of not more than one thousand dollars (\$1,000) per violation. Any person who, after notice and an opportunity for hearing, violates an order issued pursuant to this section is guilty of a misdemeanor. The department shall adopt regulations that specify the requirements for providing notice to persons to whom orders are issued and for administrative hearings and fines concerning these orders.

118335 - Inspection

(a) In order to carry out the purpose of this part, any authorized representative of the enforcement agency may do any of the following:

(1) Enter and inspect a facility for which a medical waste permit or registration has been issued, for which a medical waste permit or registration application has been filed, or that is subject to registration or permitting requirements pursuant to this part. Enter and inspect a vehicle for which a hazardous waste hauler registration has been issued, for which an application has been filed for a hazardous waste hauler, or that is subject to registration requirements pursuant to this part.

(2) Inspect and copy any records, reports, test results, or other information related to the requirements of this part or the regulations adopted pursuant to this part.

(b) The inspection shall be made with the consent of the owner or possessor of the facilities or, if consent is refused, with a warrant duly issued pursuant to Title 13 (commencing with Section 1822.50) of Part 3 of the Code of Civil Procedure. However, in the event of an emergency affecting the public health or safety, an inspection may be made without consent or the issuance of a warrant.

(c) Any traffic officer, as defined in Section 625 of the Vehicle Code, and any peace officer, as defined in Section 830.1 or 830.2 of the Penal Code, may enforce Chapter 6 (commencing with Section 118000) and this chapter, and for purposes of enforcing these chapters, traffic officers and these peace officers are authorized representatives of the department.

118340 - Unauthorized Actions / Criminal Penalty

(a) No person shall transport, store, treat, dispose, or cause the treatment or disposal of medical waste in a manner not authorized by his or her permit or registration, this part, or the regulations adopted pursuant to this part.

(b) Any person who stores, treats, disposes, or causes the treatment or disposal of medical waste in violation of this part or the regulations adopted pursuant to this part is guilty of a public offense as follows:

(1) For a small quantity generator, a first offense is an infraction and is punishable by a fine of not more than one thousand dollars (\$1,000).

(2) For a person other than a small quantity generator, a first offense is a misdemeanor punishable by a fine of not less than two thousand dollars (\$2,000), or by up to one year in county jail, or by both the fine and imprisonment.

(c) A person who is convicted of a second or subsequent violation of subdivision (a) within three years of the prior conviction shall be punished by imprisonment in the county jail for not more than one year or by imprisonment in state prison for one, two, or three years or by a fine of not less than five thousand dollars (\$5,000), or more than twenty-five thousand dollars (\$25,000), or by both the fine and imprisonment. This section shall not apply unless any prior conviction is charged in the accusatory pleading and admitted by the defendant or found to be true by the trier of fact. If the defendant is a corporation that operates medical facilities in more than one geographic location, this subdivision shall apply only if the offense involves an adjacent facility involved in the prior conviction.

(d) Any person who knowingly treats or disposes, or causes the treatment or disposal of, medical waste in violation of this part shall be punished by imprisonment in the county jail for not more than one year or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code for one, two, or three years, or by a fine of not less than five thousand dollars (\$5,000), or more than twenty-five thousand dollars (\$25,000), or by both the fine and imprisonment.

(e) This section does not apply to a person transporting medical waste who is required to be a registered hazardous waste transporter. Those persons are subject to penalties for violations pursuant to Article 8 (commencing with Section 25180) of Chapter 6.5 of Division 20.

118345 - False Statements / Failure to Register

(a) Any person who intentionally makes any false statement or representation in any application, label, tracking document, record, report, permit, registration, or other document filed, maintained, or used for purposes of compliance with this part that materially affects the health and safety of the public is liable for a civil penalty of not more than ten thousand dollars (\$10,000) for each separate violation or, for continuing violations, for each day that the violation continues.

(b) Any person who fails to register or fails to obtain a medical waste permit in violation of this part, or otherwise violates any provision of this part, any order issued pursuant to Section 118330, or any regulation adopted pursuant to this part, is liable for a civil penalty of not more than ten thousand dollars (\$10,000) for each violation of a separate provision of this part or, for continuing violations, for each day that the violation continues.

Chapter 11 - Suspension or Revocation

118350 - Grounds for Suspension or Revocation

The enforcement agency may suspend, amend, or revoke any medical waste permit issued by the enforcement agency for any of the following reasons:

(a) Violation by the permittee of any of the provisions of this part or any regulation adopted pursuant to this part.

(b) Violation of any term or condition of the permit.

(c) Aiding, abetting, or permitting the violation specified in subdivision (a) or (b) or interference in the performance of the duty of the enforcement officer.

(d) Proof that the permittee has intentionally made false statements, or failed to disclose fully all relevant facts, in any material regard, on the application for a medical waste permit.

(e) The conviction of a permittee, or the person in charge of the activity subject to the medical waste permit, of any crime that is substantially related to the qualifications or duties of the permittee or the person in charge of the activity, or that is substantially related to the functions that are subject to the medical waste permit.

For purposes of this section, a conviction means a plea or verdict of guilty or a conviction following a plea of nolo contendere. An action to revoke or suspend the medical waste permit may be taken when the time for appeal has elapsed or the judgment of conviction has been affirmed on appeal. That action may also be taken when an order granting probation is made suspending the imposition of sentence, notwithstanding any subsequent order pursuant to Section 1203.4 of the Penal Code. The enforcement agency shall take into account all competent evidence of rehabilitation furnished by the permittee or person in charge of the permitted activity.

(f) A change in any condition that requires either a temporary or permanent modification, reduction, or termination of the permitted operation to bring it into compliance with the requirements of this part and the regulations adopted pursuant to this part.

118355 - Proceedings

Proceedings conducted by the department for the suspension or revocation of a medical waste permit shall commence with the filing of any accusation and shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted to a department in that chapter.

118360 - Temporary Permit Suspension

The enforcement agency may temporarily suspend a medical waste permit prior to any hearing, when it has determined that this action is necessary to protect the public welfare. The enforcement agency shall notify the permittee of the temporary suspension and the effective date thereof and, at the same time, shall serve the permittee with an accusation.

Upon receipt of a notice of defense by the permittee, the matter shall, within 15 days, be set for hearing. The hearing shall be held as soon as possible, but not later than 30 days after receipt of the notice.

The temporary suspension shall remain in effect until the hearing is completed and the enforcement agency has made a final determination on the merits. However, the temporary suspension is vacated if the enforcement agency fails to make a final determination on the merits within 60 days after the original hearing has been completed.