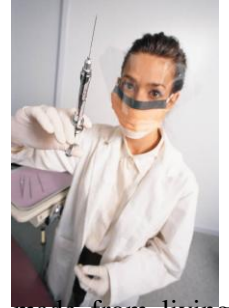


MEDICAL WASTE GUIDELINES

What does the law define as "medical waste"?

Under the law, medical waste means waste which meets *both* of the following requirements:

- It must be composed of waste which is generated or produced as a result of:
 - ✦ Diagnosis, treatment, or immunization of human beings or animals;
 - ✦ Research pertaining to such diagnosis, treatment, or immunization;
 - ✦ The production or testing of biologicals. "Biologicals" are medicinal preparations made from living organisms and their products, including, but not limited to, serums, vaccines, antigens, and antitoxins; or
 - ✦ The removal of a regulated waste from a trauma scene by a trauma scene waste management practitioner.
- The waste must be either:
- Biohazardous waste; or Sharps waste. (Health & Safety Code §117690.)



Medical waste does not include:

- Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomit, unless they contain fluid blood or originate from humans or animals with highly communicable diseases.
- Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood (i.e., dried blood) and other medical solid waste products commonly found in health care facilities. Cal-OSHA recently has allowed such waste containing wet blood (e.g., bloody gauze) that is left to dry to be disposed of as non-hazardous waste.
- Hazardous waste, radioactive waste, or household waste, including home generated sharps waste. However, starting September 1, 2008, home sharp products shall be regulated as well. (Health & Safety Code §118286.) (Hazardous and radioactive wastes need to be disposed of in accordance with laws governing those specific waste streams.)
- Waste generated in food processing or biotechnology that does not contain an infectious agent.
- Waste generated in biotechnology that does not contain human or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans. (Health & Safety Code §117700.)

What is "biohazardous waste"?

Biohazardous waste means any of the following:

- Laboratory waste which includes (but is not necessarily limited to):
 - ✦ Cultures from medical and pathological laboratories;
 - ✦ Cultures and stocks of infectious agents from research and industrial laboratories; and
 - ✦ Wastes from the production of bacteria, viruses, or the use of spores, discarded live and attenuated vaccines used in human care or research, discarded animal vaccines, including only brucellosis, contagious ecthyma, and other animal vaccines, as identified by DHS, and culture dishes and devices used to transfer, inoculate, and mix cultures.
- Human surgery specimens or tissues removed at surgery or autopsy, which the attending physician suspects of being contaminated with infectious agents known to be contagious to humans.



- Animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.
- Waste which, at the point of transport from the generator's site, at the point of disposal or thereafter, contains recognizable fluid blood, fluid blood products, containers, or equipment containing blood that is fluid, or blood from animals known to be infected with diseases which are highly communicable to humans.
- Waste containing discarded materials contaminated with excretion, exudate or secretions from humans who are required to be isolated to protect others from highly communicable diseases, or isolated animals known to be infected with diseases which are highly communicable to humans.
- Waste which is hazardous only because it is comprised of human surgery specimens or tissues which have been fixed in formaldehyde or other fixatives, or only because the waste is contaminated through contact with, or having previously contained, trace amounts of chemotherapeutic agents. Such contaminated items may include gloves, disposable gowns, towels, and intravenous solution bags and attached tubing which are empty. Biohazardous wastes that meet the conditions of this subdivision are **not** subject to the Hazardous Waste Control Act but are to be managed as medical waste and treated by incineration.
- Waste that is hazardous only because it is comprised of pharmaceuticals. "Pharmaceuticals" are prescriptions or over-the-counter human or veterinary drugs that are not already regulated under the federal Resource Conservation and Recovery Act or the Radiation Control Law. Biohazardous waste that meets the conditions of medical waste is not also subject to the laws governing hazardous waste control. (Health & Safety Code §117635.)

Urine or stool specimens sent to a lab for culturing are biohazardous waste once ready to be disposed of. However, urine and stool specimens may be disposed of down the sanitary sewer system. The employee should use appropriate precautions when disposing of the material. Stool specimens that consist of a card smear are not considered biohazardous waste and can be disposed of as solid waste in the regular trash.

What is "sharps waste?"

Sharps waste includes any device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, all of the following:

- Hypodermic needles, hypodermic needles with syringes, blades, and needles with attached tubing, syringes contaminated with biohazardous waste, acupuncture needles, and root canal files.
- Broken glass items, such as blood vials contaminated with other biohazardous waste. Any item capable of cutting or piercing that is contaminated with trauma scene waste. (Health & Safety Code §117755.)



How are pharmaceutical wastes treated?

Biohazardous waste includes pharmaceuticals not regulated by the Federal Resource Conservation and Recovery Act (RCRA; 42 U.S.C. §§6901 *et seq.*), or the low-level radioactive waste program. (Health & Safety Code §§114960 *et seq.*) Pharmaceuticals are defined to include prescription or OTC human or veterinarian drugs. (Health & Safety Code §117747.) For medical waste management purposes, pharmaceuticals do not include controlled substances. As pharmaceuticals are exempted from the hazardous waste law, DPH, rather than the Department of Toxic Substance Control, regulates these materials.



Pharmaceutical waste is subject to several requirements. Labeling and storage requirements are simplified: Rigid containers and red bags are not required. Pharmaceutical waste must be segregated and labeled "INCINERATION ONLY." As this indicates, this type of waste is to be incinerated, thermally destroyed, or otherwise treated using a DPH-approved technique. Pharmaceutical waste may be stored onsite for up to ninety (90) days without obtaining prior approval from DPH. For persons generating less than ten (10) pounds of pharmaceutical waste per year, such waste may be stored onsite for up to one year without prior approval from DPH.



How are controlled substances treated?

Controlled substances are not considered pharmaceuticals for medical waste management purposes. Hence, the federal Drug Enforcement Agency (DEA), not DPH, regulates them. To dispose of controlled substances, physicians must submit a form to the Special Agent in Charge of the local DEA office and await further instructions. (21 C.F.R. §1307.21.) The DEA Form 41, an interactive or downloadable form, can be accessed at www.dea diversion.usdoj.gov/21cfr_reports/surrend. The instructions on the current version (9/01) are incorrect and Instruction Number 5 should be disregarded.

Alternatively, physicians may opt to contract with an authorized reverse distributor (which has its own DEA registration number) to dispose of controlled substances. Physicians may contact their local DEA office with questions or information on reverse distributors.

According to DEA staff, once a controlled substance is dispensed to a patient, the DEA or the federal Controlled Substances Act no longer regulates it. Hence, the patient may dispose of his or her own controlled substance medication without DEA approval. Medications should be disposed of in such a manner that does not allow the controlled substance to be easily retrieved, pursuant to the DPH requirements discussed above.

As a physician or other DEA registrant, how do I report breakage or spillage of controlled substances?

According to the DEA, breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage, or some other form of destruction, any **recoverable** controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process. The DEA recommends that any registrant seeking to dispose of controlled substances first contact the local DEA office for disposal instructions. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA.

If the breakage or spillage is **not recoverable**, the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory of records indicating what they witnessed. The submission of a DEA Form 41 is not required for non-recoverable controlled substances.

Am I responsible for storing medical waste in a "secured" place?

Yes. The law requires that the area used for the storage of medical waste containers be secured so as to deny access to unauthorized persons and be marked with warning signs on, or adjacent to, the exterior of entry doors, gates, or lids.

The law is explicit regarding warning signs. The wording must be in English "CAUTION—BIOHAZARDOUS WASTE STORAGE AREA—UNAUTHORIZED PERSONS KEEP OUT," and in Spanish, "CUIDADO— ZONA DE RESIDUOS—BIOLOGICOS 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. Warning signs installed before April 1, 1991, which were consistent with the infectious waste law (Health & Safety Code §25117.5) as it read on December 31, 1990, satisfy the current legal requirements until the sign is either changed or moved. All signs must be readily legible during daylight from a distance of at least twenty-five (25) feet. (Health & Safety Code §118310.) A person generating more than twenty (20) pounds of biohazardous waste per month may not store that waste for more than seven (7) days. (Health & Safety Code §118280.)

How must medical waste be containerized?

Whether medical waste is stored in a separate storage facility or is kept in the facility or medical office where the waste was generated, certain requirements to contain the waste are applicable. Following are the general requirements:

- Medical waste must be contained separately from other waste. (Health & Safety Code §118276(a).)
- Effective January 1, 2007, medical waste that is stored in an area prior to transfer to the designated accumulation area, must be stored in an area that is either locked or under direct supervision or surveillance. These storage areas must be marked with the international biohazardous symbol or signage as discussed above. These signs must be readily legible from a distance of five (5) feet. (Health & Safety Code §118307.)
- Biohazardous waste must be contained in a red biohazard bag labeled with the words "Biohazardous Waste" or with the international biohazard symbol and word "BIOHAZARD." (Health & Safety Code §118275(b).)



- Bags must be tied to prevent leakage or expulsion of contents. (Health & Safety Code §118280(a).)
- Biohazardous waste contaminated through contact with chemotherapeutic agents must be segregated and labeled "Chemotherapy Waste" or "CHEMO." (Health & Safety Code §118275(d)(1).)
- Biohazard bags are to be placed for storage, handling or transport in a rigid container which may be disposable, reusable or recyclable. Containers must 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 and must be labeled with the words "Biohazardous Waste" or with the international biohazard symbol. (Health & Safety Code §118280(b).)
- Biohazardous waste cannot be stored above 0° centigrade (32° Fahrenheit) for more than seven days or below 0° centigrade for more than ninety (90) days. The enforcement agency has the discretion to approve longer storage at these temperatures but may also require more frequent removal if uncontrolled odor poses a public nuisance. (Health & Safety Code §§118275, 118280(d).) A person generating less than twenty (20) pounds of biohazardous waste per month may store it onsite above 0° centigrade for **thirty (30) days** if the facility is able to control the odor.
- Medical Waste, including biohazardous and sharps waste, may be consolidated in a common container as long as the waste is treated by an approved extreme high heat technology. The container must be labeled with the biohazardous waste symbol and the words "HIGH HEAT ONLY," or other approved label, on the lid and the sides so that it is visible from any lateral direction. (Health & Safety Code §118275(h).)

When does the accumulation time on red bag waste begin, when the first item is placed in the bag or when the bag is tied off for removal?

The seven-day accumulation time for red bag waste begins when the bag is first used.

Who can haul medical waste?

All medical wastes must be hauled by either a registered hazardous waste hauler or by a person with an "approved limited-quantity exemption." (Health & Safety Code §118025.)

What are the penalties for failure to comply with the Medical Waste Management Act?

A violation of provisions regarding storage, treatment, and/or disposal of medical waste is punishable as follows:

- For a small quantity generator, a first offense is an infraction for which a fine of as much as \$1,000 may be imposed.
- For a large quantity generator, a first offense is a misdemeanor and is punishable by a fine of not less than \$2,000, or by up to one (1) year imprisonment, or by both a fine and imprisonment.
- Subsequent violations within three (3) years of a prior conviction are punishable by imprisonment for up to three (3) years and/or by a fine not less than \$5,000 or more than \$25,000.

The use of harsher penalties also apply to any one who **knowingly** treats or disposes of medical waste in violation of the Act, even if it is only the first offense. (Health & Safety Code §118340.)

Furthermore, liability for a civil penalty of as much as \$10,000 may be imposed on any one who:

- Intentionally makes a false statement or representation in any application, label, tracking document, report, record, permit, registration, or other document filed or maintained to comply with the Medical Waste management Act which materially affects the health and safety of the public; or
- Fails to register or fails to obtain a medical waste permit in violation of the Medical Waste Management Act. (Health & Safety Code §118345.)