MEDICAL WASTE

Public Act and Rules Governing Disposal of Medical Waste

BIOHAZARD
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PART 138, MEDICAL WASTE REGULATORY ACT, OF THE MICHIGAN PUBLIC HEALTH CODE, 1978 PA 368, AS AMENDED

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MEDICAL WASTE REGULATORY ACT
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PART 138, MEDICAL WASTE REGULATORY ACT, OF THE MICHIGAN PUBLIC
HEALTH CODE, 1978 PA 368, AS AMENDED

333.13801 Short title.
Sec. 13801. This part shall be known and may be cited as the "medical waste regulatory act".

333.13803 Meanings of words and phrases; general definitions and principles of construction.
Sec. 13803. (1) For purposes of this part, the words and phrases defined in sections 13805 and 13807 have the meanings ascribed to them in those sections.
(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

333.13805 Definitions; A to M.
Sec. 13805. (1) "Advisory council" means the interdepartmental medical waste advisory council created in section 13827.
(2) "Autoclave" means to sterilize using superheated steam under pressure.
(3) "Decontamination" means rendering medical waste safe for routine handling as solid waste.
(4) "Fund" means the medical waste emergency response fund created in section 13829.
(5) "Health facility or agency" means that term as defined in section 20106.
(6) "Household" means a single detached dwelling unit or a single unit of a multiple dwelling.
(7) "Infectious agent" means a pathogen that is sufficiently virulent so that if a susceptible host is exposed to the pathogen in an adequate concentration and through a portal of entry, the result could be transmission of disease to a human.
(8) "Medical waste" means any of the following that are not generated from a household, a farm operation or other agricultural business, a home for the aged, or a home health care agency: (a) Cultures and stocks of infectious agents and associated biologicals, including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture dishes, and related devices.
(b) Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids.
(c) Pathological waste.
(d) Sharps.
(e) Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals.

333.13807 Definitions; P to T.
Sec. 13807. (1) "Pathogen" means a microorganism that produces disease.
(2) “Pathological waste” means human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery or autopsy or other medical procedure, and not fixed in formaldehyde.

(3) “Point of generation” means the point at which medical waste leaves the producing facility site.

(4) “Producing facility” means a facility that generates, stores, decontaminates, or incinerates medical waste.

(5) “Release” means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing of medical waste into the environment in violation of this part.

(6) “Response activity” means an activity necessary to protect the public health, safety, welfare, and the environment, and includes, but is not limited to, evaluation, cleanup, removal, containment, isolation, treatment, monitoring, maintenance, replacement of water supplies, and temporary relocation of people.

(7) “Sharps” means needles, syringes, scalpels, and intravenous tubing with needles attached.

(8) “Storage” means the containment of medical waste in a manner that does not constitute disposal of the medical waste.

(9) “Transport” means the movement of medical waste from the point of generation to any intermediate point and finally to the point of treatment or disposal. Transport does not include the movement of medical waste from a health facility or agency to another health facility or agency for the purposes of testing and research.


333.13809 Producing facility not incinerating medical waste on site; containment of medical waste.

Sec. 13809. A producing facility that does not incinerate medical waste on site shall do all of the following to contain medical waste: (a) Package, contain, and locate medical waste in a manner that protects and prevents the medical waste from release at the producing facility or at any time before ultimate disposal.

(b) Separate the categories of medical waste at the point of origin into appropriate containers that are labeled as required under subdivision (c).

(c) Label the containers required under subdivision (b) with a biohazard symbol or the words "medical waste" or "pathological waste" in letters not less than 1 inch high.

(d) Not compact or mix medical waste with other waste materials before decontamination, incineration, and disposal.

(e) If decontaminated medical waste is mixed with other solid waste, clearly label the container to indicate that it contains decontaminated medical waste.

(f) Store medical waste in such a manner that prevents putrefaction and also prevents infectious agents from coming in contact with the air or with individuals.

(g) If medical waste is stored outside of the producing facility, store the medical waste in a secured area or locked in a container that weighs more than 500 pounds and prevent access to the area of container by vermin or unauthorized individuals.

(h) Not store medical waste on the premises of the producing facility for more than 90 days.

333.13810 Producing facility incinerating medical waste on site; containment of medical waste.

Sec. 13810. A producing facility that incinerates medical waste on site shall do all of the following to contain medical waste: (a) Package, contain, and locate medical waste in a manner that protects and prevents the medical waste from release at the producing facility or at any time before ultimate disposal.

(b) Separate and dispose of sharps in the manner described in section 13811(d).

(c) Label the containers required under subdivision (a) with a biohazard symbol or the words “medical waste” or “pathological waste” in letters not less than 1 inch high.

(d) Not store medical waste on premises of the producing facility for more than 90 days.


333.13811 Storage, decontamination, and disposal of medical waste.

Sec. 13811. A producing facility shall store, decontaminate, and dispose of medical waste pursuant to the following: (a) Cultures and stocks of material contaminated with an infectious agent shall be stored in closed, puncture-resistant containers, decontaminated by autoclaving or incineration, and disposed of in a sanitary landfill.

(b) Blood and blood products and body fluids shall be disposed of by 1 or more of the following methods:

(i) Flushing down a sanitary sewer.
(ii) Decontaminating by autoclaving or incineration.
(iii) Solidifying.
(iv) If not in liquid form, transferring to a sanitary landfill.
(v) A process approved by the department.

(c) Pathological waste shall be disposed of by 1 or more of the following methods:

(i) Incineration or cremation.
(ii) Grinding and flushing into a sanitary sewer.
(iii) Burial in a cemetery, if transported in leakproof containers of sufficient integrity to prevent rupture.
(iv) Grinding until rendered unrecognizable, stored in closed, puncture-resistant, properly labeled containers, and, if not in liquid form, disposed of in a sanitary landfill.
(v) A process approved by the department.

(d) Sharps shall be disposed of by 1 of the following methods: (i) Placement in rigid, puncture-resistant containers that are appropriately labeled and transported to a sanitary landfill in a manner that retains the integrity of the container.

(ii) Incineration or decontamination and grinding that renders the objects unrecognizable. Ground sharps shall be placed in a sealed, rupture-resistant container and transported to a sanitary landfill.

(iii) A process approved by the department.

(e) Animal waste contaminated with organisms infectious to humans shall be disposed of by incineration or by burial in a sanitary landfill in properly labeled, double containers that are leakproof and puncture-resistant and are tightly sealed to prevent escape of fluids or material. Contaminated animal organs disposed of separately shall be rendered unrecognizable.

333.13813 Producing facility; registration form; medical waste management plan required; registration fee; certificate of registration; investigation of complaint; inspection of facility; disposition of fees.

Sec. 13813. (1) Each producing facility shall register with the department on a form prescribed by the department. A producing facility shall have a written medical waste management plan that contains information required in section 13817 on file on the premises within 90 days after registration.

(2) A producing facility shall submit the following registration fee with the registration form: (a) For a producing facility that is a private practice office with fewer than 4 licensees under article 15 who are physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians employed by, under contract to, or working at the producing facility, a registration fee of $50.00.

(b) For a producing facility that is a private practice office with 4 or more licensees under article 15 who are physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians employed by, under contract to, or working at the producing facility, a registration fee of $20.00 for each licensee, up to a maximum total registration fee of $80.00.

(3) Upon receipt of a complete registration form and registration fee under this section or section 13815, the department shall issue a certificate of registration to the producing facility. A certificate of registration issued under this section is valid for 3 years from its date of issuance. The department shall investigate each complaint received and may inspect a producing facility registered under this section pursuant to the receipt of a complaint.

(4) Registration fees collected pursuant to this section and section 13815 shall be forwarded to the state treasury and deposited pursuant to section 13829.


333.13815 Registration fee.

Sec. 13815. A producing facility shall submit the following registration fee with the registration form required under section 13813: (a) For a producing facility that is a health facility or agency other than a hospital described in subdivision (b) and for a producing facility that is not a health facility or agency, a registration fee of $75.00.

(b) For a producing facility that is a health facility or agency that is a hospital with 150 or more licensed beds or a clinical laboratory, a registration fee of $150.00.


333.13817 Medical waste management plan; contents; compliance; update; availability.

Sec. 13817. (1) The medical waste management plan required in section 13813 shall contain information relating to the handling of all medical waste generated, stored, decontaminated, or incinerated at each producing facility or transported from the producing facility for handling by another facility for storage, decontamination, incineration, or for disposal in a sanitary landfill, cemetery, or other disposal site. A professional corporation may identify and prepare a common medical waste management plan for all producing facilities owned and operated by the corporation. The medical waste management plan shall describe each of the following, to the extent the information is applicable to the producing facility:
(a) The types of medical waste handled.
(b) The segregation, packaging, labeling, and collection procedures used.
(c) The use and methods of on-site or off-site storage.
(d) The use and methods of on-site or off-site decontamination.
(e) The use of on-site or off-site incineration.
(f) The corporate or other legally recognized business name of solid waste haulers who transport medical waste for the producing facility.
(g) The use of sanitary landfills, cemeteries, and other disposal sites.
(h) The measures to minimize exposure of the facility’s employees to infectious agents throughout the process of handling and disposing of the medical waste, including, where applicable, the use of protocols, procedures and training, personal protective devices and clothing, physical containment or isolation devices or systems, and prevention or control of aerosols.
(i) The name of the individual responsible for the management of the medical waste.
(2) A medical waste management plan shall comply with the requirements of this act.
(3) A producing facility shall update a medical waste management plan each time there is a change in either of the following, within 30 days after the change occurs: (a) A person or site named in the plan.
(b) The types of medical waste handled or the methods of handling medical waste at the facility.
(4) Upon request, a producing facility shall make its medical waste management plan available to the department pursuant to a routine or unannounced inspection or the investigation of a complaint.
(5) Upon receipt of 24 hours’ advance notice, a producing facility shall make its medical waste management plan available to an employee of the producing facility for inspection on the premises or provide a copy of the medical waste management plan to the employee.
(6) A producing facility shall comply with its medical waste management plan.

333.13819 Medical waste management plan; modification; warning.
Sec. 13819. (1) Upon review of a medical waste management plan under section 13817(4), the department may require a producing facility to modify the medical waste management plan at any time the department determines the plan is not adequate to protect the public health or is inconsistent with state or federal law. Upon determining that the plan is inadequate or inconsistent under this section, the department shall notify the producing facility in writing of its determination and the specific modifications necessary for compliance. The producing facility shall modify the plan within 10 days after receipt of the notice from the department.
(2) The department may issue a warning to a producing facility that fails to modify a plan within the 10-day period.

333.13821 Manner of packaging medical waste.
Sec. 13821. A producing facility that transports medical waste off the premises of the producing facility shall package the medical waste in the following manner:
(a) Sharps that are not ground or incinerated as described in section 13811(d) shall be contained for disposal in individual leakproof, rigid, puncture-resistant containers that are secured to preclude loss of the contents. In addition, a container used to store or transport a number of individual sharps containers shall be leakproof. These containers shall be conspicuously labeled with the word “sharps”. Sharps that are contained pursuant to this subdivision may be disposed of as solid waste pursuant to part 115 (solid waste management) of the natural resources and environmental protection act, Act No. 451 of the Public Acts of 1994, being sections 324.11501 to 324.11549 of the Michigan Compiled Laws. However, sharps shall not be compacted or handled during transport in a manner that will result in breakage of a sharps container.

(b) Medical waste other than sharps shall be contained in bags other than body pouches or other containers that are impervious to moisture and have a strength sufficient to resist ripping, tearing, breaking, or bursting under normal conditions of usage or handling. The bags or containers shall be secured so as to prevent leakage during storage, handling, or transport.


333.13823 Investigation and confirmation of reported medical waste on land or water; report; protective measures; consultations; information on results of investigation.

Sec. 13823. (1) If suspected medical waste is discovered on any land or water in the state and reported to the department of natural resources, the department of public health, a local health department, the department of state police, or any other state or local governmental agency, the agency or department receiving the report shall promptly investigate to confirm the existence of medical waste. If the existence of medical waste is confirmed by a department or agency other than the department of natural resources, a report shall be transmitted immediately to the department of natural resources. The department of natural resources may, if appropriate, take measures to contain the medical waste, to close off the area, to remove the medical waste from the environment, and to do all things necessary to protect the public health, safety, and welfare and the environment. The department of natural resources may, if appropriate, conduct an investigation to determine the source of the medical waste.

(2) The department of natural resources may consult with the department of public health, the appropriate local health department, the department of state police, and the department of attorney general on the actions taken by the department of natural resources under this section.

(3) After the department of natural resources confirms the existence of medical waste under this section, the department of natural resources shall inform the legislature, the governor, the advisory council, and the public on the results of any investigation conducted within 30 days after the investigation is completed.


333.13825 Investigation and confirmation of violation; report; corrective and protective measures; consultations; assistance; information on results of investigation.

Sec. 13825. (1) If there is a suspected violation of this part on the premises of a health facility or agency or on the premises of an incinerator owned and operated by a
health facility or agency, the department of public health shall promptly conduct an investigation to confirm the violation. If the suspected violation is reported to the department of natural resources, a local health department, the department of state police, or any other state or local governmental agency, the report immediately shall be transmitted to the department of public health. If the investigation confirms the existence of a violation of this part, the department of public health may, if appropriate, take measures to correct the violation and to do all things necessary to protect the public health, safety, and welfare and the environment.

(2) The department of public health may consult with the department of natural resources, the appropriate local health department, the department of state police, and the department of attorney general on the actions taken by the department of public health under this section. If the suspected violation of this part is at an incinerator owned and operated by a health facility or agency, the department of public health immediately shall notify the department of natural resources and request the assistance of the department of natural resources in conducting the investigation.

(3) If the department of public health confirms the existence of a violation under this section, the department of public health shall inform the legislature, the governor, the advisory council, and the public on the results of the investigation conducted within 30 days after the investigation is completed.


333.13827 Interdepartmental medical waste advisory council; creation; appointment and qualifications of members; chairperson; duties of advisory council.

Sec. 13827. (1) The interdepartmental medical waste advisory council is created in the department. The council shall consist of the following members appointed as follows:

(a) One individual appointed by the director of public health representing the department.

(b) One individual appointed by the director of the department of natural resources representing the department of natural resources.

(c) One individual appointed by the director of the department of state police representing the department of state police.

(d) One individual appointed by the director of commerce representing the department of commerce, who has knowledge of tourism in the state.

(e) One individual appointed by the attorney general representing the department of the attorney general.

(2) The representative of the department shall serve as chairperson.

(3) The advisory council shall do all of the following: (a) Collect data pertaining to medical waste reports and investigations under this part.

(b) Annually report to the governor, the standing committees in the senate and house of representatives with jurisdiction over public health matters, the department of public health, and the department of natural resources on all of the following:

(i) The number of medical waste reports received and investigations conducted under this part.

(ii) The implementation and effectiveness of this part.
(iii) Changes in the overall regulatory scheme pertaining to medical waste, including, but not limited to, the enactment of pertinent federal law.

(iv) Recommendations, if any, that the advisory council has for changes to this part or any other state statute or rule that pertains to medical waste.

(v) Coordinate reports and investigations under this part between the department of public health and the department of natural resources.


333.13829 Medical waste emergency respond fund; creation; deposits; investments; interest and earnings; no reversion to general fund; use of fund.

Sec. 13829. (1) The medical waste emergency response fund is created in the state treasury.

(2) The state treasurer shall deposit in the fund all money received pursuant to this act and all money received by the fund as otherwise provided by law.

(3) The state treasurer shall direct the investment of the fund. Interest and earnings of the fund shall be credited to the fund. Money in the fund at the close of the fiscal year shall remain in the fund and shall not revert to the general fund.

(4) Not more than 80% of the total amount in the fund shall be used by the department of public health for administrative expenses related to the implementation of this part, and the balance may be used by the department of natural resources for response activities necessitated by the release of medical waste into the environment.


333.13830 Rules to prescribe training standards.

Sec. 13830. (1) The department shall promulgate rules to prescribe training standards for both medical and nonmedical personnel who handle medical waste in producing facilities.

(2) Each producing facility shall train its personnel who handle medical waste pursuant to the rules promulgated under subsection (1).


333.13831 Violation; administrative fine; failure to register or have plan available for inspection; injunction.

Sec. 13831. (1) Except as provided in subsection (2), a person who violates this part or a rule promulgated under this part is subject to an administrative fine of not more than $2,500.00 for each violation and an additional fine of not more than $1,000.00 for each day during which the violation continues. For a first offense, the department of public health or the department of natural resources may postpone the levying of a fine under this subsection for not more than 45 days or until the violation is corrected, whichever occurs first.

(2) A person who fails to register with the department or have a medical waste management plan available for inspection in compliance with sections 13813 and 13817 is subject to an administrative fine of $500.00.

(3) A person who violates this act may be enjoined by a court of competent jurisdiction from continuing the violation.

R 325.1541 Definitions.
Rule 1. As used in these rules:
(A) "Act" means the medical waste regulatory act, part 138 of Act No. 368 of the Public Acts of 1978, as amended, being §§333.13801 to 333.13831 et seq. of the Michigan Compiled Laws.
(B) "Categories of medical waste," as defined in §13805(8) of the act, shall be considered as waste when the items are ready to be disposed. Sharps shall be considered as a medical waste and disposed of under §13811(d) of the act whether or not they have become contaminated with an agent infectious to humans.
(C) "Contiguous property" means the same or geographically adjacent property that may be divided by a public or private right-of-way. Parcels of property connected by a right-of-way which the property owner controls and to which the public does not have access shall also be considered as contiguous property.
(D) "Stained with blood or body fluids," as used in §13805(8)(b) of the act, means the contaminated item cannot release blood or body fluids in a liquid or semiliquid state when compressed, or caked and dried blood or body fluids are not capable of being released when handled.
(E) "Syringes," as included in the definition of "sharps" under §13807(7) of the act, includes all syringes with an attached needle and those parts of a syringe, with or without an attached needle, that are contaminated with a potentially infectious agent. Needles shall only be removed from a syringe in accordance with the procedures established by R 325.70007(2)(e) adopted under section 24 of Act No. 154 of the Public Acts of 1974, as amended.

R 325.1542 Packaging, labeling, storage, and transportation.
Rule 2. (1) In addition to the requirements established in section 13821 of the act, containers used for packaging, shipping, and transportation of regulated medical waste shall comply with the requirements of Michigan's motor carrier safety act, Act No. 181 of the Public Acts of 1963, as amended, being §§480.11 to 480.22 of the Michigan Compiled Laws.
(2) Identifying labels that are placed on containers containing decontaminated medical waste mixed with other solid waste, as required in §13809(e) of the act, shall be a minimum of 1 inch high.

(3) The 90-day period for "storage" of medical waste, as required in §§13809(h) and 13810(d) of the act, shall begin when use of the storage container is initiated.

(4) When being transported to a sanitary landfill for disposal, packaged medical waste that is not decontaminated shall not be mixed with non-medical wastes.


R 325.1543 Treatment of medical waste.

Rule 3. (1) Blood and blood products and body fluids that are solidified, but not decontaminated during the solidification process, shall be packaged and disposed of as medical waste as specified in §§13809, 13811(b), and 13821(b) of the act.


R 325.1544 Equipment maintenance; record retention.

Rule 4. (1) Medical waste producing facilities shall perform testing of their decontamination or sanitization equipment to demonstrate the continued effective operation of the equipment. Testing frequency and procedures shall be pursuant to the manufacturer's recommendations or methods and frequencies approved by the department.

(2) Facilities shall retain and make available testing data and results from the most recent test performed for inspection by the department.

(3) Testing frequency and procedures shall be contained in the producing facility's medical waste management plan.


R 325.1545 Registration of multiple producing facilities; medical waste management plan content; registrations for school districts; registration fee.

Rule 5. (1) Multiple producing facilities that are owned by 1 entity and located on contiguous property that is owned by the same entity, such as college campuses and large hospital corporations, may register under one registration. The registrant shall maintain a list of the location of all producing facilities located upon the contiguous properties and the type of medical waste produced at each respective facility. The registrant shall maintain the list of producing facilities and their respective types of medical waste in the registrant's medical waste management plan. Each producing facility shall have a copy of the medical waste management plan on site.

(2) A school district, private school, or charter school system that generates or stores medical waste shall register as a medical waste producing facility. The name and location of all schools producing medical waste within the school district, private school, or charter school system and the type or types of medical waste produced or stored at the respective schools shall be contained in the school district, private school, or charter school system medical waste management plan. A school district, private school, or charter school shall maintain a copy of the plan at each school producing medical waste.
(3) The applicable multiple facility, or school district, private school, or charter school system registration fee shall be the greater of the fees established in §13813(2) or §13815 of the act that would apply to any individual facility located on the contiguous property or school within the school district, private school, or charter school system if it is registered separately.


R 325.1546 Fee payment for producing facilities with expired registrations; change of ownership.

Rule 6. (1) Registration fee payments received from producing facilities with expired registrations shall have the fees applied by the department back to the date when the last registration expired.

(2) If a change in ownership of a producing facility occurs, then the new owner shall notify the department and register as a new producing facility and pay the designated fee in accordance with §13813(1) and (2) of the act.


R 325.1547 Training requirement; training schedule; record of training.

Rule 7. (1) Each facility that produces medical waste shall provide instruction in the proper handling of medical waste according to the facility’s medical waste management plan to its employees who generate and/or dispose of medical waste. The plan shall be in compliance with the requirements prescribed in §13817 of the act.

(2) A facility shall assure that an employee who handles medical waste is trained before the employee assumes duties that involve the handling of medical waste to enable the employee to handle and dispose of medical waste in a safe and proper manner.

(3) A facility shall assure that current employees who handle medical waste are trained within 90 days after the effective date of these rules. A facility shall assure that a new employee is trained before assuming duties that involve the handling of medical waste to enable the employee to handle and dispose of medical waste in a safe and proper manner. All employees shall receive refresher training when a change in the producing facility’s medical waste management plan occurs that directly affects the employee’s duties.

(4) A facility that produces medical waste shall create and retain a record of the training of employees who handle medical waste. The record shall include all of the following information with respect to each employee:

(a) Employee’s name.
(b) Job classification.
(c) Dates of training.

(5) A facility that produces medical waste shall retain its training records for a minimum period of 3 years.


R 325.1548 Remedies and penalties.

Rule 8. A person who violates any of the provisions of these rules shall be subject to the remedies and penalties under the act.

R 325.1549  Contested cases; applicable law.
