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BILL



ANALYSIS

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House Bill 4459 (Substitute S-1 as reported)
Sponsor: Representative Fred Miller
House Committee: Regulatory Reform
Senate Committee: Health Policy

Date Completed: 10-19-10

RATIONALE

The handling and disposal of medical waste is regulated under Part 138 of the Public Health Code. Part 138, which is known as the Medical Waste Regulatory Act, was enacted in 1990. Over the past few years, representatives of the Department of Natural Resources and Environment (DNRE) met with stakeholders to identify provisions in Part 138 that should be updated to reflect the way the medical waste program is administered currently and to accommodate industry changes regarding medical waste management. It has been suggested that the workgroup's recommendations be incorporated in statute.

CONTENT

House Bill 4459 (S-1) would amend **Part 138 (Medical Waste)** of the Public Health Code to revise provisions applicable to facilities that generate, store, decontaminate, remove, or transport medical waste ("producing facilities"). Specifically, the bill would do the following:

- **Revise the definition of "producing facility".**
- **Revise requirements regarding the storage and disposal of specific types of medical waste.**
- **Require a medical waste treatment technology to be approved by the DNRE.**
- **Revise registration fees for different types of producing facilities.**
- **Revise the information that must be included in a producing facility's medical waste management plan, and require a facility to update its plan at least every three years.**

- **Revise requirements for reporting the discovery of medical waste.**
- **Eliminate the Interdepartmental Medical Waste Advisory Council, and transfer its duties to the DNRE.**
- **Allow the Medical Waste Emergency Response Fund to be used for programs relating to medical waste reduction, management, and education.**
- **Change existing administrative fines for violations to civil fines, and require the revenue to be deposited in the State's General Fund.**
- **Allow a court to require a violator to pay the value of damage to natural resources; and require the money to be deposited in the General Fund.**
- **Allow a court to require a violator to pay costs incurred by the State or a local unit; and allocate the money to the Medical Waste Emergency Response Fund or the local unit.**
- **Authorize the DNRE to issue a cease and desist order if a violation were causing an imminent public health hazard or threat to the environment.**
- **Provide that a violator would be guilty of a misdemeanor punishable by imprisonment for up to six months and/or a maximum fine of \$1,000.**

Producing Facility

Part 138 defines "producing facility" as a facility that generates, stores, decontaminates, or incinerates medical waste. The bill would include in the definition a facility that removes or transports medical waste, and delete the reference to incineration. The term also

would include a transfer station where medical waste is stored and a trauma scene waste management practitioner. The term would not include a funeral home that does not practice embalming and does not generate medical waste, a home health care agency, a household, a farm operation or other agricultural business, or a facility licensed by the Department of Human Services that provides residential care services, such as adult and child foster family and group homes, child day care centers, child care institutions, child or adult foster care camps, and homes for the aged.

"Medical waste" means any of the following:

- 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.
- Liquid human and animal waste, including blood and blood products and body fluids, but excluding urine or materials stained with blood or body fluids.
- Pathological waste.
- Sharps.
- Waste from animals used in research that have been exposed to an infectious agent.

The bill would refer to toxins, rather than biologicals, in the provision regarding cultures and stocks. Regarding research animal waste, the bill would include carcasses, body parts, blood, body fluids, or other material contaminated with the infectious agent.

Part 138 defines "pathological waste" as human organs, tissues, body parts other than teeth, products of conception, and fluid that are removed by trauma or during surgery, and that are not fixed in formaldehyde or other fixative agent. Under the bill, pathological waste would not include a particular organ, body part, or tissue removed by trauma or during surgery, autopsy, or other medical procedure that is not known to be or is not highly likely to be contaminated with an infectious agent and that is requested by an individual to be returned for religious, ethnic, or personal reasons.

Off-Site Decontamination

Currently, a producing facility that does not incinerate medical waste on site must ensure that certain requirements are met to contain medical waste. The bill would refer to a facility that does not decontaminate medical waste, rather than one that does not incinerate it.

Under these conditions, the facility may not compact or mix medical waste with other waste materials before decontamination, incineration, and disposal; if decontaminated medical waste is mixed with other solid waste, the container must be labeled clearly to indicate that it contains decontaminated medical waste. The bill would delete these provisions. The bill would require that medical waste that was being packaged for final decontamination or disposal be segregated from other waste materials.

Under the Code, medical waste may not be stored on the producing facility's premises for more than 90 days. The bill specifies that the storage period would begin when the use of the storage container was initiated. Separate provisions would apply to a producing facility that generated only sharps as medical waste.

The bill would prohibit transfer station storage containers from being stored for more than seven days without approval from the DNRE. The bill also would require trauma scene waste being transported in a trauma scene vehicle to be stored so that it was physically separated by partition or compartments and would not present a cross-contamination hazard to the decontamination equipment and supplies stored and transported in the same vehicle.

Medical waste would have to be packaged and transported in accordance with applicable U.S. Department of Transportation (USDOT) hazardous material regulations, and USDOT medical waste shipping paper records would have to be retained in accordance with applicable regulations.

On-Site Decontamination

Under Part 138, a producing facility that incinerates medical waste on site must ensure that certain requirements are met to contain medical waste. The bill would refer

to a facility that decontaminates, rather than incinerates, medical waste.

In addition to the current requirements, the bill would require that medical waste be sorted and separated by type into appropriate containers.

Producing Facility Requirements

Cultures & Stocks. Currently, cultures and stocks of material contaminated with an infectious agent must be stored in closed, puncture-resistant containers, decontaminated by use of an autoclave or incinerator, and disposed of in a landfill. Under the bill, this material also could be subjected to a decontamination and disposal process approved by the DNRE.

Blood & Body Fluids. Blood, blood products, and body fluids must be disposed of by a process approved by the DNRE, flushing down a sanitary sewer, decontamination by autoclaving or incineration, solidification, or, if not in liquid form, transfer to a sanitary landfill. The bill would delete the last three methods and instead would refer to decontamination, by use of an autoclave or incinerator; and solidification then decontamination, by use of an autoclave or incinerator, and disposal in a landfill.

Pathological Waste. Pathological waste must be disposed of by one or more of the following methods:

- Incineration or cremation.
- Grinding and flushing into a sanitary sewer.
- Burial in a cemetery, if transported in leakproof containers.
- Grinding until rendered unrecognizable; stored in closed, puncture-resistant properly labeled containers; and, if not in liquid form, disposal in a sanitary landfill.
- A process approved by the DNRE.

Under the bill, instead, the waste would have to be disposed of by one of the following methods:

- Incineration and disposal in a landfill.
- Cremation.
- Grinding and flushing into a sanitary sewer.

- Burial in a cemetery, if packaged and transported in accordance with USDOT requirements.
- A decontamination and disposal process approved by the DNRE.

Sharps. Part 138 requires sharps to be disposed of by one of the following methods:

- Placement in rigid, puncture-resistant containers that are labeled appropriately and transported to a sanitary landfill in a manner that retains the integrity of the container.
- Incineration or decontamination and grinding that renders the objects unrecognizable.
- A process approved by the DNRE.

Ground sharps must be placed in a sealed, rupture-resistant container and transported to a sanitary landfill.

Under the bill, instead, sharps would have to be disposed of by one of the following methods:

- Disposal in a landfill if packaged and transported in accordance with USDOT requirements.
- Decontamination, by use of an autoclave or incinerator, and disposal in a landfill.
- A decontamination and disposal process approved by the DNRE.

Animal Waste. Currently, animal waste contaminated with an infectious agent must be disposed of by incineration or by burial in a sanitary landfill in properly labeled, double containers that are leakproof, puncture-resistant, and tightly sealed. Contaminated animal organs disposed of separately must be rendered unrecognizable. The bill would delete these provisions. Instead, the waste would have to be disposed of by one of the following methods:

- Decontamination, by use of an autoclave or incinerator, and disposal in a landfill.
- Disposal in a landfill if packaged and transported in accordance with USDOT requirements.
- A decontamination and disposal process approved by the DNRE.

Medical Waste Treatment Technology

The bill would require a medical waste treatment technology used by a producing

facility to meet the Code's requirements to attain a minimum level of decontamination to protect public health, safety, and welfare, and the environment as established by DNRE rules.

A medical waste treatment technology could not be installed or used unless it had been reviewed and approved by the DNRE. The Department would have to review the technology for compliance with Part 138 and rules promulgated under it.

Upon request, the DNRE would have to give the manufacturer an application form for evaluation and review of the technology. The application would have to be completed and submitted to the Department with supportive documentation as part of the request for review and approval. The DNRE would have to review the application and documentation, and approve the application if the technology complied with Part 138 and rules. Otherwise, the Department would have to deny it. If the application were denied, the DNRE would have to specify the reasons for the denial and what additional information was needed for approval.

The manufacturer would have to give the DNRE the name and address of each producing facility where the approved waste treatment technology would be installed. The equipment could not be used until on-site efficacy and validation testing were completed successfully. Approval of a treatment technology by the DNRE would be for the use of the technology as a medical waste treatment method only. The producing facility would be responsible for securing any other permits or required approvals needed for the technology from other agencies or DNRE programs.

Producing Facility Registration; Fees

Under Part 138, a producing facility must register with the DNRE, and submit the following registration fee with the registration form:

- For a producing facility that is a private practice office with fewer than four licensees who are physicians, dentists, podiatrists, nurse practitioners, nurse midwives, or veterinarians employed by, under contract to, or working at the producing facility, \$50.

- For a producing facility that is a private practice office with four or more of the specified licensees employed by, under contract to, or working at the facility, \$20 for each licensee, up to a total fee of \$80.

In the first category, the bill would delete the reference to a "private practice office". In both categories, the bill would refer to licensees or registrants and would include physician assistants and acupuncturists among the specified health professionals. The bill also would eliminate the \$20-per-person fee for a facility with at least four licensees (or registrants) and prescribe a flat \$80 fee.

In addition, the bill would establish the following registration fees:

- For a producing facility that was a hospital with at least 150 licensed beds or a laboratory, \$150.
- For all other producing facilities that were health facilities or agencies, \$75.

For a facility that was not a health facility or agency, including a body art facility, medical waste treatment facility, medical waste collection and transport company, blood draw station, blood or blood product collection facility, funeral home, animal control shelter, pharmacy, or school district, the registration fee would be \$75.

A life support agency that did not store medical waste would not have to register as a producing facility. A mobile health care unit, such as a bloodmobile or a licensed ambulance, that was owned and operated by a registered facility in a fixed location would be considered to be included under the registration of that facility.

Currently, upon receiving a complete registration form and fee, the DNRE must issue a certificate of registration to the producing facility. Under the bill, this provision would apply unless the Department determined that the facility was not in compliance with Part 138 or rules promulgated under it.

A public sharps collection program would have to register as a medical waste producing facility but would be exempt from payment of any registration fee.

Medical Waste Management Plan

Part 138 requires a producing facility to have a written medical waste management plan on file on the premises within 90 days after registering with the DNRE. The bill also would require a copy of the common plan to be kept available at each producing facility site for inspection by the Department.

Among other things, a medical waste management plan must describe the corporate or other legally recognized business name of solid waste haulers who transport medical waste for the producing facility. Under the bill, instead, the plan would have to describe the corporate or other legally recognized business name, address, and telephone number of medical waste disposal service companies that transported or treated medical waste for the facility.

A medical waste management plan also must describe the use of sanitary landfills, cemeteries, and other disposal sites. The bill instead would require the plan to describe the name and address of landfills, cemeteries, and other disposal sites to which medical waste was directly taken by the producing facility.

The bill also would require a plan to describe cleanup methods and procedures to be used in response to spills of medical waste.

Currently, a producing facility must update its medical waste management plan within 30 days each time there is a change in a person or site named in the plan, or the types of medical waste handled or the methods of handling the waste at the facility. Under the bill, a facility would have to update its plan every three years or within 30 days of a change.

Part 138 authorizes the DNRE to require a producing facility to modify its medical waste management plan at any time the Department determines that the plan is not adequate to protect the public health or is inconsistent with State or Federal law. Under the bill, the Department also could require a facility to modify its plan if the plan were not adequate to protect public safety and welfare, and the environment. Currently, the facility must modify its plan within 10 days after receiving notice from

the Department, and the DNRE may issue a warning to a facility that fails to do so. Under the bill, instead, the facility would have to modify the plan within the time period specified by the Department in its notice.

Compliance Determination

The bill would authorize the DNRE, upon presentation of proper identification, at reasonable times to enter upon public or private property upon which medical waste was reasonably believed to be located, with the permission of the property's owner or custodian, to determine compliance with Part 138 or a rule promulgated under it.

If the DNRE had reasonable or probable cause to believe that a violation was being committed on private or public property, or that evidence of a violation existed on the property, and the owner or custodian denied permission to enter, the Department could apply for a warrant commanding the sheriff or other law enforcement officer, with the Department's aid, to search the property and seize any medical waste that was possessed, controlled, or used wholly or partially in violation of Part 138 or a rule promulgated under it, or any evidence of a violation.

Disposal as Solid Waste; Hazardous Waste

Part 138 prescribes specific requirements and procedures for the packaging of medical waste by a producing facility that transports the waste off the premises. These provisions apply to sharps that are not ground or incinerated and to medical waste other than sharps. The bill would delete these provisions. Instead, medical waste that was decontaminated and packaged in accordance with the bill could be disposed of as solid waste pursuant to Part 115 (Solid Waste Management) of the Natural Resources and Environmental Protection Act (NREPA).

Hazardous waste, as defined in Section 11103 of NREPA, could not be disposed of as medical waste. (That section defines "hazardous waste" as waste or a combination of waste and other discarded material, including solid, liquid, semisolid, or contained gaseous material, that because of its quantity, quality, concentration, or physical, chemical, or infectious

characteristics may cause or contribute significantly to an increase in mortality or an increase in serious irreversible illness or serious incapacitating but reversible illness, or may pose a substantial present or potential hazard to human health or the environment if improperly treated, stored, transported, disposed of, or otherwise managed.)

Reporting Suspected Medical Waste

Currently, if suspected medical waste is discovered on any land or water in Michigan and reported to the DNRE, the Department of Community Health (DCH), a local health department, the Michigan State Police (MSP), or any other State or local governmental agency, the agency or department receiving the report must investigate promptly to confirm the existence of medical waste. If the existence is confirmed by a department or agency other than the DNRE, a report must be transmitted immediately to the DNRE. The bill would delete these requirements. Instead, any person who discovered suspected medical waste on any land or water in Michigan would have to report it to the DNRE.

The bill would retain provisions allowing the Department to take measures to contain or remove the waste, and conduct an investigation to determine the source of the medical waste.

Currently, the DNRE may consult with the DCH, the appropriate local health department, the MSP, and the Department of Attorney General on the actions taken by the DNRE. After the DNRE confirms the existence of medical waste, it must inform the Legislature, the Governor, the Interdepartmental Medical Waste Advisory Council, and the public on the results of any investigation within 30 days. The bill would delete these provisions.

Violations of Part 138

Current provisions related to the investigation of suspected violations contain references to the DCH. They require the DCH to take certain actions, including notifying the Legislature, the Governor, the Interdepartmental Medical Waste Advisory Council, and the public of the results of an investigation confirming the existence of a

violation. The bill would delete all of these provisions. Instead, if the DNRE suspected that a producing facility had violated Part 138 or rules promulgated under it, the Department promptly would have to conduct an investigation to confirm it.

Currently, if the investigation confirms the existence of a violation, the DCH may take measures to correct it and protect the public health, safety, welfare, and environment. Under the bill, this provision would apply to the DNRE rather than the DCH.

Interdepartmental Medical Waste Advisory Council

The Advisory Council consists of one individual representing each of the following Departments, appointed by the applicable Director: Community Health; Natural Resources and Environment; State Police; Energy, Labor, and Economic Growth; and Attorney General.

The bill would eliminate the Advisory Council and transfer its duties to the DNRE. The Advisory Council's duties include collecting data pertaining to medical waste reports and investigations under Part 138, and reporting annually to the Governor and the standing committees of the Senate and House of Representatives with jurisdiction over public health matters on the number of medical waste reports received and investigations conducted, the implementation and effectiveness of Part 138, changes in the overall regulatory scheme pertaining to medical waste, and recommendations for changes to statute or rule.

Medical Waste Emergency Response Fund

The Fund exists within the State Treasury and the State Treasurer must deposit in the Fund money received under the Code and as otherwise provided by law. The bill would require the State Treasurer to deposit in the Fund all money received pursuant to Part 138, except for civil fines, payments for damage to natural resources, and criminal fines for violations of Part 138; and all money designated for the Fund as otherwise provided by law.

The DNRE would be the administrator of the Fund for auditing purposes.

Currently, up to 80% of the Fund may be used for administrative expenses related to the implementation of Part 138. The DNRE may use the balance for response activities addressing the release of medical waste into the environment. The bill would add programs relating to medical waste reduction, management, and education to the authorized uses. Also, Fund money could be spent only upon appropriation.

Penalties for Part 138 Violations

Under current law, a person who violates Part 138 or a rule promulgated under it is subject to an administrative fine of up to \$2,500 for each violation and an additional fine of up to \$1,000 for each day the violation continues. For a first offense, the DCH or the DNRE may postpone the levying of a fine for up to 45 days or until the violation is corrected, whichever occurs first.

A person who fails to register with the DNRE or have a medical waste management plan available for inspection is subject to an administrative fine of \$500.

In addition, a person who commits a violation may be enjoined by a court from continuing the violation.

The bill would delete all of these provisions. Instead, the DNRE could request that the Attorney General bring an action in the name of the people of Michigan for any appropriate relief, including injunctive relief, for a violation of Part 138 or Part 138 rules. In addition to any other relief, the court could impose on any violator a civil fine as follows:

- A maximum civil fine of \$2,500 for each violation and an additional civil fine of up to \$1,000 for each day the violation continued.
- A civil fine of \$500 for failure to register with the DNRE, or failure to make a medical waste management plan available to the DNRE as required.

Additionally, the court could order a violator to pay an amount equal to all of the following:

- Costs to contain, remove, or dispose of medical waste or take action necessary to protect public health, safety, or welfare or the environment incurred by

the State or a local unit of government as a result of the violation.

- Costs of surveillance or enforcement incurred by the State or a local unit as a result of the violation.
- The full value of damage done to the State's natural resources.

Civil fine revenue and money collected for damage to natural resources would have to be deposited in the State's General Fund. Money collected for costs incurred by the State or a local unit of government would have to be deposited in the Medical Waste Emergency Response Fund. If a local unit incurred costs, however, the court could order that money collected instead be forwarded to that local unit.

The DNRE could issue a cease and desist order to correct a violation of Part 138 or rules if the violation were causing an imminent public health hazard or threat to the environment.

A person who violated Part 138, a rule promulgated under it, or a final order would be guilty of a misdemeanor punishable by imprisonment for up to six months and/or a maximum fine of \$1,000, plus any payment ordered to reimburse the State or a local unit or to compensate for damage to natural resources. Each day that a violation occurred would be a separate offense.

Part 138 Rules

Currently, the DNRE must promulgate rules to prescribe training standards for both medical and nonmedical personnel who handle medical waste in producing facilities. Each producing facility must train its personnel who handle medical waste pursuant to the rules. The bill would delete these provisions. Instead, the bill would allow the DNRE to promulgate rules to implement Part 138.

MCL 333.13805 et al.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The bill would modernize the Medical Waste Regulatory Act based on sound science with

regard to the generation, transportation, storage, and disposal of medical waste. Also, the bill would provide specificity as to which entities, such as trauma scene waste managers, acupuncturists, and body art facilities, would be subject to regulation. Apparently, trauma scene cleanup sometimes is conducted by janitorial or carpet cleaning services; the proper removal and disposal of trauma scene waste, however, goes beyond the routine work performed by such companies. Because of the presence of blood-borne pathogens, extra measures must be taken to protect public health and safety. Reportedly, some companies operating as trauma scene waste managers have disposed of biohazardous waste in neighborhood trash containers, essentially creating a second crime scene that requires the use of law enforcement resources. The bill's registration requirements would help ensure that only qualified companies performed this work and that they were subject to DNRE oversight.

Under the bill, the DNRE would have explicit authority to enter property to investigate suspected violations, while the requirement for a search warrant under certain circumstances would protect property rights and prevent unnecessary intrusion. In addition, the bill would reallocate some of the money received from violators to the State's General Fund and to local governments to cover their costs in enforcing the law. The changes proposed by the bill would strengthen the State's medical waste program and further protect public health and the environment.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would require facilities that produce medical waste to register with the Department and follow certain procedures when disposing of that waste. The bill also would require certain facilities to pay a registration fee. Currently, some regulated facilities already pay this fee; the bill would expand the fee base as follows:

Type of Facility	Fee
Facility with fewer than 4 acupuncturists, or physicians assistants	\$50
Facility with 4 or more acupuncturists or physician assistants	\$80
Health facility – not a hospital	\$75
Hospital	\$150
Other producing facilities – not health facilities	\$75

The Department would collect an indeterminate amount of revenue from these fees, which would be deposited in the Medical Waste Emergency Response Fund. The Fund received about \$207,000 in FY 2008-09 and would likely collect considerably more than that under the bill.

The bill would establish a civil fine of \$500 for failure to register as a producer of medical waste. Additionally, violators could be ordered to pay for costs associated with their violation, including cleanup of medical waste, monitoring and enforcement, and the value of damage done to the natural resources of the State. Revenue from civil fines and payments for damage to natural resources would go to the General Fund. Reimbursement for costs would go to the Medical Waste Emergency Response Fund, except when a local government incurred costs as a result of a violation. In that case, the local government could be reimbursed for its costs.

In addition, the bill would establish a penalty system that could lead to an increase in misdemeanor convictions related to the improper disposal of medical waste product. Local governments would incur the costs of incarceration in local facilities, which vary by county.

Fiscal Analyst: Matthew Grabowski
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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.