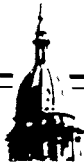


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BILL ANALYSIS

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Senate Fiscal Agency

• Lansing, Michigan 48909

• (517) 373-5383

MAR 08 1990

Michigan State Legislature

House Bill 4136 (Substitute S-1 as reported)
House Bill 4137 (Substitute H-5 as reported without amendment)
House Bill 4142 (as reported without amendment)
Sponsor: Representative Teola P. Hunter (H.B. 4136)
Representative James A. Kosteva (H.B. 4137)
Representative Michael J. Bennane (H.B. 4142)

House Committee: Public Health
Senate Committee: Health Policy

Date Completed: 2-6-90

RATIONALE

Public concern in Michigan over the handling and disposal of medical debris was aroused in the summer of 1988 with reports of hypodermic syringes and other medical waste washing up on Lake Michigan shorelines in Oceana and Mason Counties and the temporary closing of beaches in Oceana County. These incidents were among a number of occurrences from around the country that involved the disposal of medical waste: the discovery of used hypodermic syringes on Lake Erie beaches in Cleveland; the closing of beaches in New York and New Jersey due to medical debris, including syringes that contained blood infected with the virus that causes Acquired Immune Deficiency Syndrome (AIDS) washing ashore; and, reports of children in Indiana found playing with waste contaminated with the human immunodeficiency virus (the cause of AIDS) from the illegal dumping of medical waste in an alley dumpster. Such incidents have raised questions about the handling, containment, and disposal of medical waste in Michigan.

CONTENT

House Bill 4136 (S-1)

The bill would create the "Medical Waste

Regulatory Act" in the Public Health Code to:

- Require a producing facility to register with the Department of Public Health (DPH) and have a written medical waste management plan
- Establish registration fees.
- Require a producing facility that transported medical waste off its premises to package the medical waste in a manner prescribed in the bill.
- Establish procedures for investigating reports of suspected medical waste violations, permit measures to be taken to control the waste and correct a violation, and establish penalties for violations.
- Establish the Independent Medical Waste Advisory Council.
- Create the Medical Waste Emergency Response Fund.
- Require the DPH to promulgate rules prescribing the training standards for persons who handle medical waste in producing facilities.

H.B. 4136, etc. (2-6-90)

The bill would take effect 90 days after being enacted. The bill is tie-barred to Senate Bill 69, which would amend the Public Health Code to prescribe procedures for the containment, decontamination, storage, and disposal of medical waste.

House Bill 4137 (H-5)

The bill would amend Public Act 245 of 1929, which created the Water Resources Commission, to:

- Make any unauthorized discharge of medical waste into the waters of the State prima facie evidence of a violation of the Act and subject the person responsible to the Act's penalties.
- Establish minimum and maximum civil fines for violations of the Act.
- Upgrade intentional violations of the Act from misdemeanors to felonies.
- Establish additional mandatory fines for civil and criminal defendants, and mandatory imprisonment for criminal defendants, found to be liable for substantial endangerment of the public health, safety, or welfare.
- Delete current provisions and enact similar provisions on the actions that may be taken against suspected polluters and the recourse available to those affected by an order of abatement or the issuance of a permit.
- Revise provisions on the use of waters of the State for sewage or other waste disposal purposes, including increasing from 60 to 180 days after receipt of a permit application the time the Commission has to grant or deny a permit.

The bill would take effect 90 days after being enacted. The bill is tie-barred to House Bill 4136.

House Bill 4142

The bill would amend the Occupational Code, as it pertains to the licensure of funeral establishments and the practice of

mortuary science, to provide that a person would be subject to the penalty provisions of the Code if the person failed to comply with medical waste regulations, as proposed in House Bill 4136. The Department of Licensing and Regulation, in consultation with the Director of Public Health, would be required to promulgate rules to prescribe training standards for licensees and nonlicensees who handled infectious medical waste in a funeral establishment. A licensee who owned or operated a funeral establishment would be required to train his or her employees pursuant to the rules promulgated by the Department.

The bill would take effect 90 days after being enacted, and is tie-barred to House Bill 4136 and Senate Bill 69.

MCL 339.1810

Following is a detailed description of House Bills 4136 (S-1) and 4137 (H-5).

House Bill 4136 (S-1)

Registration and Fees

Each producing facility would be required to register with the DPH on a prescribed form. (The bill does not contain a definition of "producing facility". As defined in Senate Bill 69 (H-3), "producing facility" would mean a facility that generates, stores, decontaminates, or incinerates medical waste). The following registration fees would have to be submitted with a registration form:

- \$50 for a private practice office with fewer than four licensees under Article 15 of the Public Health Code who were physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians who were employed by, under contract to, or working at the producing facility.
- \$20 for each licensee up to a maximum of \$80 for a private practice office with four or more licensees who were physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, or veterinarians employed by, under contract to, or working at the

producing facility.

Registration fees would have to be forwarded to the State Treasury and deposited in the "Medical Waste Emergency Response Fund".

Upon receipt of a complete registration form and fee, the DPH would be required to issue a certificate of registration to the producing facility. A registration certificate would be valid for three years. The Department would be required to investigate each complaint received and could inspect a registered producing facility upon receiving a complaint.

Management Plan

Each producing facility would be required to have a written medical waste management plan on file on the premises within 90 days of registration. The medical waste management plan would have to 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 could identify and prepare a common medical waste management plan for all producing facilities owned and operated by the corporation.

The management plan would have to describe each of the following to the extent that the information was applicable to the producing facility:

- The types of medical waste handled.
- The segregation, packaging, labeling, and collection procedures used.
- The use and methods of on-site or off-site storage and decontamination.
- The use of on-site or off-site incineration.
- The corporate or other legally recognized business name of solid waste haulers who transported medical waste for the producing facility.
- The use of sanitary landfills, cemeteries, and other disposal sites.
- The measures used 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.

- The name of the person responsible for the medical waste management.

A producing facility would be required to comply with its medical waste management plan, and to update a management plan each time there was a change in either of the following within 30 days after the change occurred: a person or site named in the plan, or the types of medical waste handled or the methods of handling medical waste at the facility.

A producing facility would be required to make its medical waste management plan available, upon request, to the Department pursuant to a routine or unannounced inspection or the investigation of a complaint. Upon 24 hours' advance notice, a producing facility would have to make its management plan available to an employee of the producing facility for inspection on the premises or provide a copy of the management plan to the employee.

Upon review of a management plan, the DPH could require a producing facility to modify the plan at any time the Department determined that the plan was not adequate to protect the public health or was inconsistent with State or Federal law. Upon determining that the plan was inadequate or inconsistent, the DPH would be required to notify the producing facility in writing of its determination and specific modifications needed for compliance. The producing facility would have to modify the plan within 10 days after receipt of the Department's notice. The DPH could issue a warning to a producing facility that failed to modify a plan within the 10-day period.

Packaging Medical Waste

A producing facility that transported medical waste off the facility's premises would have to package the waste in the following manner:

- Sharps that were not ground or incinerated, in the manner described in

Senate Bill 69, would have to be contained in individual leakproof, rigid, puncture-resistant containers that were secured to preclude loss of the contents. A container used to store or transport a number of individual sharps containers would have to be leakproof. Containers would have to be labeled conspicuously with the word "sharps". Sharps that were contained pursuant to the bill could be disposed of as solid waste pursuant to the Solid Waste Management Act. Sharps could not be compacted or handled during transport in a manner that would result in breakage of a sharps container.

- Medical waste, other than sharps, would have to be contained in bags other than body pouches or other containers that were impervious to moisture and were strong enough to resist ripping, tearing, breaking, or bursting under normal conditions of use or handling. The bags or containers would have to be secured so as to prevent leakage during storage, handling, or transport.

Discovery of Medical Waste

If suspected medical waste were discovered on any land or water in the State and reported to the Department of Natural Resources (DNR), the DPH, a local health department, the Department of State Police, or any other State or local governmental agency, the agency or Department that received the report would be required to investigate promptly to confirm the existence of medical waste. If the existence were confirmed by a Department or agency other than the DNR, a report would have to be transmitted immediately to the DNR. The DNR could, if appropriate, take measures to contain the medical waste, close off the area, remove the medical waste from the environment, and do all things necessary to protect the public health, safety, and welfare, and the environment. If appropriate, the DNR could conduct an investigation to determine the source of the medical waste.

The DNR could consult with DPH, the appropriate local health department, the State Police, and the Attorney General on the actions taken by the DNR. After the DNR confirmed the existence of medical waste, the DNR would

be required to notify the Legislature, the Governor, the Interdepartmental Medical Waste Advisory Council, and the public on the results of any investigation conducted within 30 days after the investigation was completed.

Suspected Violations

If there were a suspected violation of the bill 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 DPH would be required to conduct promptly an investigation to confirm the violation. If the suspected violation were reported to the DNR, a local health department, the State Police, or any other State or local governmental agency, the report would have to be transmitted immediately to the DPH. If the investigation confirmed the existence of a violation, the DPH, if appropriate, could take measures to correct the violation and to do all that was necessary to protect the public health, safety, and welfare, and the environment.

The DPH could consult with the DNR, the State Police, and the Attorney General on the actions taken by the DPH. If the suspected violation were at an incinerator owned and operated by a health facility or agency, the DPH would be required to notify the DNR immediately and request that Department's assistance in conducting the investigation. If the DPH confirmed the violation, the Department would be required to inform the Legislature, the Governor, the Interdepartmental Medical Waste Advisory Council, and the public on the results of the investigation conducted within 30 days after it was completed.

Advisory Council

The Interdepartmental Medical Waste Advisory Council would be created in the Department of Public Health. The council would consist of the following appointed members: one person appointed by each of the Directors of the Departments of Public Health, Natural Resources, State Police and Attorney General who would represent the appointing Department; plus, one person appointed by the Director of the Department of Commerce, who would represent the Department and who had knowledge of tourism in the State. The DPH

representative would serve as council chairperson.

The Council would be required to collect data pertaining to medical waste reports and investigations and report annually to the Governor, the standing committees in the Senate and House of Representatives that had jurisdiction over public health matters, the DPH, and the DNR on all of the following:

- The implementation and effectiveness of the bill's provisions.
- Changes in the overall regulatory scheme pertaining to medical waste, including, but not limited to, the enactment of pertinent Federal law.
- Recommendations, if any, that the Advisory Council had for changes to the bill's provisions or any other State statute or rule that pertained to medical waste.
- Coordinate reports and investigations under these provisions between the DPH and the DNR.

Emergency Response Fund

The bill would create the Medical Waste Emergency Response Fund in the State Treasury. The State Treasurer would be required to deposit in the Fund all money received pursuant to the proposed Act and all money received by the Fund as otherwise provided by law. The State Treasurer would be required to direct the investment of the Fund, with the Fund's interest and earnings being credited to the Fund. Money in the Fund at the close of the fiscal year would remain in the Fund and could not revert to the General Fund. Up to 80% of the Fund's total amount could be used by the DPH for administrative expenses related to the implementation of the bill, and the balance could be used by the DNR for response activities necessitated by the release of medical waste into the environment.

Rules

The DPH would be required to promulgate rules to prescribe training standards for medical and nonmedical personnel who handle medical waste in producing facilities. Each producing facility would be required to train its personnel who handle medical waste pursuant

to the rules.

Penalties

A person who violated the bill or a rule promulgated under it would be 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 during which the violation continued. For a first offense, the DPH or the DNR could postpone levying a fine for up to 45 days or until the violation was corrected, whichever occurred first. A person who failed to register with the DPH or have a medical waste management plan available for inspection would be subject to an administrative fine of \$500. A person who violated the proposed Act could be enjoined by a court of competent jurisdiction from continuing the violation.

Proposed MCL 333.13801 - 333.13831

House Bill 4137 (H-5)

Evidence of a Violation

Unless authorized by permit, order, or rules of the Water Resources Commission or the DNR, the discharge in State waters of any medical waste, as defined in the Public Health Code as proposed in Senate Bill 69, would be prima facie evidence of a violation of Public Act 245 (i.e., the burden would be on the alleged violator to rebut the evidence), and would subject the person responsible to the penalties prescribed in the Act.

Unlawful Pollution of Waters

Currently, the Act provides that whenever the Water Resources Commission is of the opinion that a person is causing or about to cause unlawful pollution of State waters, the Commission is permitted to notify the alleged offender of its determination. The bill would delete references to the Commission and replace them with references to the Department. In addition, the Department would be permitted to enter an order requiring the person, who was causing or about to cause unlawful pollution, to abate the pollution or refer the matter to the Attorney General for legal action, or do both. The bill would delete current provisions on the notice of determination by the Commission, the holding

of a hearing on the matter, and the disposition of a case upon agreement with the terms of the proposed permit.

The bill also would repeal the provision that authorizes the Commission to take appropriate legal action to carry out the Act and enforce pollution laws.

Contested Case Hearing

The Act currently permits a person aggrieved by a restriction of polluting content, waste, or pollution or any other order or permit of the Commission to file a sworn petition with the Commission asking for a hearing on the matter. The bill would delete these provisions and provide that a person who was aggrieved by the Department's abatement order or by the reissuance, modification, suspension, or revocation of an existing permit of the Commission executed pursuant to the Act could file a sworn petition with the Department or Commission, as appropriate, setting forth the grounds and reasons for the complaint and asking for a contested case hearing on the matter pursuant to the Administrative Procedures Act (APA). A petition filed more than 60 days after action on the order or permit could be rejected by the Department or Commission as being untimely.

Use of Waters for Waste Disposal

The Act currently requires a person who uses waters of the State for sewage or other waste disposal and who requires a new or substantial increase in the present use to file with the Commission a written statement on the nature of the contemplated development and other information on the water to be used. The bill would delete these provisions and require a person who sought a new or increased use of the waters of the State for sewage or other waste disposal purposes to file with the Commission an application setting forth the information required by the Commission, including the nature of the enterprise or development contemplated, the amount of water to be used, the water's source, the proposed point of discharge of the waste into the State's waters, the estimated amount to be discharged, and a statement setting forth the expected bacterial, physical, chemical, and other known characteristics of the wastes.

Within 60 days of receiving the statement, the Commission currently is required to issue a permit that states any restrictions the Commission considers necessary to guard against unlawful uses of the waters of the State. Under the bill, the Commission, within 180 days after receipt of a complete application, would have to grant or deny a permit, unless the applicant and the Commission agreed to extend the time period. If granted, the Commission would be required to condition the permit on restrictions, in the Commission's judgment, that could be necessary to guard against unlawful uses of the State's waters.

Under the Act, if a permit or denial is not acceptable to the user, he or she may request a hearing on the matter. The Commission's final order of determination, permit, or denial is conclusive unless reviewed in accordance with the APA. The bill provides that if the permit or denial of increased use were not acceptable to the permittee, the applicant, or any other person, any one of these persons could file a sworn petition with the Commission setting forth the grounds and reasons for the complaint and asking for a contested case hearing on the matter pursuant to the APA. A petition filed more than 60 days after action on the permit application could be rejected by the Commission as being untimely.

Violations

Currently, the Act provides that any duly appointed agent of the Commission has the authority to enforce the Act and may make a criminal complaint against any person violating the Act. Under the bill, an employee of the Department or an employee of another governmental agency appointed by the Department could, with concurrence of the Department, enforce the Act. Under the Act, the Commission may request the Attorney General to bring a civil action for appropriate relief for violation of the Act. The bill would permit the Department also to make the request of the Attorney General for violation of the Act or a permit, order, rule, or stipulation of the Department or Commission. The Act provides that in addition to any other relief that is granted the court may impose a civil penalty of up to \$10,000 per day of violation. The bill would delete this provision and provide,

instead, that the court would be required to impose a civil fine of at least \$2,500 and could award reasonable attorney fees and costs to the prevailing party. The maximum fine imposed by the court, however, could not be more than \$25,000 per day of violation.

Currently, a person is guilty of a misdemeanor if he or she discharges a substance into the waters of the State contrary to a permit, order, rule or stipulation of the Commission, makes a false statement in an application for a permit or in information required by the terms of a permit, or renders inaccurate a monitoring device or record of the Commission. The bill would increase such violations to a felony and would apply the penalty provisions to knowing or intentional violations.

Under the Act, if a conviction is for a violation committed subsequent to a first conviction, the court may impose a fine of up to \$50,000 per day of violation. The bill would require the imposition of a fine and set a minimum of at least \$25,000 per day of violation. Upon conviction, in addition to a fine, the court could sentence the defendant to prison for up to two years.

Upon a finding by the court that the actions of a civil defendant posed or had posed a substantial endangerment to the public health, safety, or welfare, the court would be required to impose, in addition to other penalties in the Act, a fine of at least \$500,000 but not more than \$5 million.

Upon a finding by the court that the action of criminal defendant posed or had posed a substantial endangerment to the public health, safety, or welfare, the court would be required to impose, in addition to other penalties in the Act, a fine of at least \$1 million and, in addition to a fine, a sentence of five years' imprisonment.

To find a defendant civilly or criminally liable for substantial endangerment under these provisions, the court would be required to determine that the defendant knowingly or recklessly acted so as to cause a danger of death or serious bodily injury and that either of the following had occurred:

-- The defendant had an actual awareness,

or belief, or understanding that his or her conduct would cause a substantial danger of death or serious bodily injury.

-- The defendant acted in gross disregard of the standard of care that any reasonable person should have observed in similar circumstances.

The bill specifies that knowledge possessed by a person other than the defendant could be attributable to the defendant if the defendant took steps to shield himself or herself from the relevant information.

Any fine or other award ordered paid pursuant to these provisions would have to be payable to the State and credited to the General Fund, and would constitute a lien on any property, of any nature or kind, owned by the defendant. A lien would take effect and have priority over all other liens and encumbrances except those filed or recorded prior to the date of judgment only if notice of the lien were filed or recorded as required by State or Federal law. A lien filed or recorded would have to be terminated according to the procedures required by State or Federal law within 14 days after the fine or other award was paid. In addition to any other method of collection, any fine or award could be recovered by right of setoff to any debt owed to the defendant by the State, including the right to a refund of income taxes paid.

Miscellaneous

The Act currently requires every person doing business in the State that discharges wastewater to the waters of the State or to any sewer system, which contains wastes in addition to sanitary sewage, annually to file certain reports. A business or industry that violates these provisions may be enjoined on petition of the Water Resources Commission to a court of proper jurisdiction. Under the bill, this action could be taken by the Attorney General and references to the Commission would be deleted.

In addition, the bill would delete several references to the Commission and replace them with references to the Department of Natural Resources.

MCL 323.2 et al.

SENATE COMMITTEE ACTION

The Senate Health Policy Committee adopted a substitute to House Bill 4136 that would: specify which licensees, under the Public Health Code, would be included in a private practice office for the purpose of determining registration fees; clarify secondary containment requirements for sharps; and, require the DPH to promulgate rules prescribing training standards for handlers of medical waste in producing facilities.

BACKGROUND

At the Federal level, on November 1, 1988, the Medical Waste Tracking Act of 1988 was signed into law. Among other things, the Act requires the U.S. Environmental Protection Agency to establish a two-year demonstration program for tracking medical waste generated in states subject to the law. The regulations establishing the program must include a list of medical wastes to be tracked and minimum standards for segregation from other wastes, packaging, and labeling before transport to treatment and/or disposal. Facilities that incinerate medical waste on-site also are subject to certain reporting requirements.

These regulations apply to medical waste generators in states that participate in the program. Under the Act, participation is mandatory for Connecticut, New Jersey, and New York. The law also included the Great Lakes states, but allowed them to opt out of the program within 30 days of the promulgation of the regulations, which gave them a deadline of April 1989. Michigan, along with the other Great Lakes states, did choose to opt out of the Federal program. Subsequently, emergency rules that were written by the DPH, in accordance with the Administrative Procedures Act, were promulgated that April. Those rules were in effect until October 1989, at which time they were given a one-time-only extension of six months.

FISCAL IMPACT

House Bill 4136 (S-1)

The bill would have an indeterminate impact

on State revenues and expenditures. Based on the assumption that there are approximately 32,500 licensees working in producing facilities that would have to register under the bill, the registration fee revenues credited to the Medical Waste Emergency Response Fund every three years would be between \$600,000 and \$1,500,000.

Of that amount 80% or between \$480,000 and \$1,200,000 on a three-year basis, would be available for appropriation to the Department of Public Health for the operation of the Medical Waste Control program. The Department of Natural Resources would have access to 20% of the revenues in the Fund, or between \$120,000 and \$300,000 on a three-year basis, for any necessary clean up activities.

The Department of Public Health projects first-year budget needs related to activities that would be required under the provisions of the bill to be approximately \$280,000 and 4 FTE positions.

The FY 1989-90 appropriation bill for the Department of Public Health contains an appropriation of 4 FTE positions and \$500,000 in fee revenues predicated on the passage of this package of bills.

House Bill 4137 (H-5)

The bill would have an indeterminate fiscal impact, since the amount of increased revenue due to larger fines or increased costs from legal action taken by the State cannot be estimated at this time.

House Bill 4142

The bill would have no fiscal impact on State or local government. (See the fiscal analysis of House Bill 4136).

ARGUMENTS

Supporting Argument

The discovery of medical debris on Michigan beaches dramatized the need for State regulation of the disposal of such wastes. In a time when medical wastes can include deadly carcinogens or even the AIDS virus, those who dispose of such wastes should be closely regulated. The bills, which would place into

law emergency rules that were developed by the DPH, represent a more comprehensive and uniform approach to medical waste management in Michigan in comparison to the indirect and fragmented regulations that previously were in effect.

Opposing Argument

While these bills would deal with certain aspects of handling and disposing of medical debris, concerns still remain that other factors involved in medical waste management, such as home health care, need to be addressed. In today's approach to medical treatment, hospital stays for patients are becoming shorter and home health care is being relied on more for care that used to be delivered in hospitals. Furthermore, the type of health care that is being administered in the home setting has become more sophisticated. Thus, home health care is a source of medical debris that is similar to the type produced in hospital settings, and because of this, the handling, containment, and disposal of such debris should be regulated. In addition, previous proposals for medical waste regulations had proposed that a manifest system be developed to track the handling of medical waste from generator to hauler to the disposal facility in order to ensure that this waste, indeed, would end up at a disposal facility and not wash up on a beach or merely be disposed of in a dumpster.

Response: With the growing reliance on home health care and the recognition of insurers' liability for such services, the issue of regulating medical debris produced in a home setting may have to be revisited in the future. As to the absence of a manifest system for tracking medical waste, some people believe that the few incidents of improper medical debris disposal do not warrant the implementation of such a system.

Legislative Analyst: L. Arasim

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G. Cutler (H.B. 4137)

H8990/S4136A

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.