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BILL ANALYSIS

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Senate Bill 69 (Substitute S-1 as passed by the Senate)
Senate Bills 70, 71, 72, and 73 (as passed by the Senate)
Sponsor: Senator Vern Ehlers (Senate Bills 69, 70, 72 & 73)
Senator John J. H. Schwarz, M.D. (Senate Bill 71)
Committee: Health Policy

Date Completed: 4-27-89

RATIONALE

Public concern in Michigan over the handling and disposal of medical debris was aroused last summer 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 immuno-deficiency virus (the cause of AIDS) from the illegal dumping of medical waste in an alley dumpster. Such incidents have raised questions about regulating the handling, containment, and disposal of medical waste in Michigan.

CONTENT

Senate Bill 69 (S-1) would amend the Public Health Code to prescribe procedures that a licensee, who owned and/or operated a private practice office or clinical laboratory, as specified in the bill, and a health facility or agency would have to follow for the containment,

decontamination, transportation, and disposal of "infectious waste" from a clinical lab, "infectious waste" from patient care services, "pathological waste", and "sharps".

Senate Bills 70 and 71 would amend the Occupational Code and the Mental Health Code, respectively, to require compliance with Senate Bill 69. Senate Bill 72 would require the Department of Public Health to promulgate rules for veterinary clinics. Senate Bill 73 would regulate the disposal of infectious waste in sanitary landfills. The four bills are tied-barred to Senate Bill 69.

Senate Bill 69 (S-1)

The bill would require compliance with the following provisions by each licensee who owned and/or operated a private practice office, a clinical laboratory licensed under Article 17 of the Code, or a clinical lab where exams were performed by the person seeking the information; a lab operated by a person licensed to practice medicine, osteopathic medicine and the treatment of patients, as well as a similar lab operated by up to five of these licensees; a lab operated by a college, university, or school approved by the Department of Education for the training of students; and, a lab operated by the Federal government (MCL 333.20507). The bill also would require the Department of Public Health to promulgate rules to implement

S.B. 69-73 (4-27-89)

these provisions.

Clinical Lab Infectious Waste

Precautions that a facility, agency, or lab would have to take under the bill would depend on the classification of the infectious waste, as follows:

- "Biosafety level 1" would mean a pathogen of no known, or minimal potential hazard to individuals and the environment.
- "Biosafety level 2" would mean a pathogen of moderate potential hazard to individuals and the environment.
- "Biosafety Level 3" would mean a pathogen that could cause serious or potentially fatal disease as a result of exposure through inhalation.

"Infectious waste" would mean waste that contained pathogens that were sufficiently virulent so that if a susceptible host were exposed to the pathogens in an adequate concentration and through a portal of entry, the result could be the transmission of disease. "Pathogen" would mean a microorganism that produced disease.

Containment. A clinical lab and a health facility or agency that owned or operated a licensed clinical laboratory would be required to do all of the following in order to contain infectious waste from the clinical lab:

- For biosafety level 2: limit access of unauthorized employees and other individuals to the clinical lab; require the use of biological safety cabinets or other personal protective or physical containment devices approved by the Department of Public Health for procedures with a high potential for creating aerosols and for concentrations or large volumes of infectious agents.
- For biosafety level 3: require the use of biological safety cabinets or other physical containment devices approved by the Department for all activities that involved a possibility of aerosol exposure; isolate the geographic location of the clinical laboratory and install in the clinical lab a double-door entry or negative air pressure system that was

approved by the Department; control the access of unauthorized employees and other individuals to the laboratory; and, install in the lab a ducted exhaust air ventilation system approved by the Department.

Decontamination. A health facility or agency and a clinical lab would be required to decontaminate infectious waste from the clinical lab as follows:

- For biosafety level 1 or 2, the health facility or agency and clinical lab would be required to incinerate or autoclave (sterilize using superheated steam under pressure) all culture stocks, tubes, slants, and petri plates and all specimen containers before disposal; could incinerate or package the infectious waste for disposal; and would have to require all protective clothing used in the clinical lab to be washed with detergent in hot water.
- For biosafety level 3, all infectious waste would have to be autoclaved in the clinical lab before disposal.

Transportation. A health facility or agency and a clinical lab would be required to transport infectious waste from the lab as follows:

- For biosafety level 1 or 2, if the waste were to be decontaminated at a site away from the lab, the infectious waste would have to be wrapped, bagged, or placed in leakproof containers.
- For biosafety level 3, the waste could not be transported outside of the health facility or agency or clinical lab in which the waste was produced. The waste would have to be placed in leakproof containers labeled to indicate a biological hazard.

Disposal. A health facility or agency and a clinical lab would have to dispose of infectious waste from the clinical lab as follows:

- For biosafety level 1 or 2: blood, urine, feces, sputum, wound drainage, and other body fluids could be disposed of through an appropriate plumbing fixture into the sanitary sewer; and, infectious waste that had been decontaminated could be

disposed of in a disposal area that was a sanitary landfill approved by the Department of Natural Resources (DNR) under the Solid Waste Management Act.

- For biosafety level 3: blood, urine, feces, sputum, wound drainage, and other body fluids would have to be autoclaved before disposal; and, infectious waste that had been autoclaved could be disposed of in an approved sanitary landfill.

The bill specifies that provisions on disposal would not apply to infectious waste that was being transported by a health facility or agency to another health facility or agency for research and testing purposes.

Patient Care Services Infectious Waste

Containment. A health facility or agency would be required to do the following in order to contain the infectious waste from patient care services, whether the infectious waste was classified in biosafety level 1, 2, or 3: require the infectious waste, as well as linen and clothing, to be contained in impervious bags; and, disinfect equipment and other surfaces that had been exposed to infectious waste.

Transportation. A health facility or agency would be required to transport infectious waste from patient care services as follows: infectious waste that was classified in biosafety level 1 or 2 would have to be wrapped, bagged, or packaged in a manner that minimized the spread of contamination during transportation; and, infectious waste that was classified in biosafety level 3 would have to be transported in covered containers that were labeled to indicate a biological hazard, and could not be transported outside of the health facility or agency.

Decontamination and Disposal. A health facility or agency would be required to decontaminate and dispose of infectious waste from patient care services as follows:

- For infectious waste that was classified in biosafety level 1 or 2: blood, urine, feces, sputum, wound drainage, and other body fluids could be disposed of through an appropriate plumbing fixture into a sanitary sewer; infectious waste other than that previously described

could be disposed of through incineration or in a sanitary landfill approved by the DNR under the Solid Waste Management Act.

- For infectious waste that was classified in biosafety level 3: the waste would have to be incinerated or autoclaved before disposal, except as otherwise provided by rule of the Department; and, if the waste had been decontaminated in this way, the health facility could dispose of it in an approved sanitary landfill; and, the health facility would have to maintain decontamination equipment within the building in which the infectious waste was produced.

Pathological Waste and Sharps

"Pathological waste" would mean body organs, tissues, parts, and fluids removed during surgery or autopsy, whether or not they were infectious. "Sharps" would mean discarded hypodermic needles, syringes, and scalpel blades, whether or not they were infectious.

Containment and Transportation. A health facility or agency would be required to do all of the following for the containment and transportation of pathological waste and sharps: place pathological waste in leakproof bags or containers that were labeled or color-coded to indicate a potential biological hazard; and place discarded sharps in rigid, puncture-resistant containers at the site of use. The containers would have to be labeled to indicate a potential biological hazard.

Decontamination and Disposal. A health facility or agency could do one of the following for the decontamination and disposal of pathological waste and sharps:

- Pathological waste could be disposed of by one of the following methods: incineration or cremation, grinding and flushing into the sanitary sewer, and burial at a recognized burial site.
- Sharps that were not classified in biosafety level 3 and decontaminated sharps could be incinerated, disposed of in a DNR-approved sanitary landfill, or transported to an out-of-State disposal area that was licensed or authorized to accept that type of waste by the

jurisdiction in which the disposal area was located. Sharps that were classified in biosafety level 3 would have to be decontaminated before disposal.

Rules

The Department would be required to promulgate rules to implement these provisions including, at a minimum, rules that categorized pathogens into biosafety levels 1 to 4 for purposes of the provisions on infectious waste from a clinical lab.

Proposed MCL 333.16266 et al.

Senate Bill 70

The bill would amend the Occupational Code to provide that a person would be subject to the penalty provisions of the Code if the person did not comply with requirements in the Public Health Code on the containment, decontamination, transportation, and disposal of infectious waste, as proposed in Senate Bill 69, in the same manner in which health facilities or agencies would be required to comply with these proposed provisions.

MCL 339.1810

Senate Bill 71

The bill would amend the Mental Health Code to require a mental hospital, psychiatric hospital, psychiatric unit, or hospital operated or licensed by the Department of Mental Health that handled "infectious waste" to comply with requirements in the Public Health Code on the containment, decontamination, transportation, and disposal of "infectious waste", as proposed in Senate Bill 69, in the same manner in which "health facilities or agencies" would be required to comply with these proposed provisions. The bill would define "health facility or agency" as defined in the Public Health Code, and "infectious waste" defined in Senate Bill 69.

Proposed MCL 330.1149b

Senate Bill 72

The bill would amend the Public Health Code to require the Department of Public Health to

promulgate rules to regulate the handling and disposal of infectious waste in private practice offices of veterinarians and in veterinary clinics. These rules would be in addition to rules proposed for promulgation under provisions of Senate Bill 69.

Proposed MCL 333.20192

Senate Bill 73

The bill would amend the Solid Waste Management Act to prohibit a person from knowingly disposing of the following in a sanitary landfill, and to prohibit an owner or operator of a sanitary landfill from knowingly permitting the disposal of the following in a sanitary landfill:

- "Infectious waste" unless the waste had been decontaminated or was not required to be decontaminated but was packaged in the manner required under the Public Health Code.
- "Pathological waste".
- "Sharps" that were not in rigid, puncture-resistant containers.

(The terms used in the bill would be defined in Senate Bill 69.)

A solid waste hauler transporting solid waste over a public road in the State would be required to comply with the bill and rules promulgated under it. The Director of the Department of Natural Resources would be required to promulgate rules pertaining to the safe transportation of infectious waste, pathological waste, and sharps.

Proposed MCL 299.413 and 299.421

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 24, 1989. According to the Director of the Office of the Great Lakes in the Department of Natural Resources, Michigan and the other of the Great Lakes states have chosen not to be covered by the Federal law.

FISCAL IMPACT

Senate Bill 69 (S-1)

The bill would have no fiscal impact on State or local government.

Senate Bill 70

The bill would have an indeterminate impact on Department of Licensing and Regulation fine revenues. The magnitude and direction of the impact would depend on the number of violations, the degree and cost of enforcement, and the number and size of fines levied.

Senate Bill 71

The bill would result in an indeterminate increased cost to the State by expanding certain precautionary controls and requiring the installation of special equipment. There are four State mental health facilities that operate a clinical laboratory, which is licensed by the State Department of Public Health. The following new requirements would result in increased costs: the use of biological safety cabinets or other physical containment devices, the installation of double-door entry into the laboratory, and the installation of a ducted exhaust air-ventilation system.

Senate Bill 72

The bill would have no fiscal impact on State or local government.

Senate Bill 73

The bill would have an indeterminate fiscal impact on State and local government by potentially expanding the caseload for law enforcement, judicial, and corrections agencies while also generating revenue through fines.

ARGUMENTS

Supporting Argument

The discovery of medical debris on Michigan beaches this past summer 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 would place into law guidelines for the handling, containment, and disposal of medical waste that the Department of Public Health issued in 1985 for facilities licensed by the Department--hospitals, nursing homes, and medical care facilities--and extend regulation of medical waste management to other generators of this waste such as mortuaries, mental hospitals and institutions, and veterinary clinics. These bills represent a reasoned response to the medical waste problem.

Opposing Argument

State regulation of medical waste is indirect and fragmented and is governed by a variety of laws with the authority to oversee medical waste management and disposal practices divided between the Departments of Natural Resources and Public Health. 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 need to be addressed. For example, some people have proposed that a manifest system be developed for tracking the handling of medical waste from the generator, to the hauler, to the disposal facility in order to assure that this waste would, indeed, end up at a disposal facility and not wash up on a beach or merely be disposed of in an dumpster. Furthermore, the bills do not call for new penalties. Stricter penalties need to be placed into law in order to deter illegal dumping of medical waste. A comprehensive approach is needed so that a program that addressed all aspects of medical waste management and disposal would be developed.

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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.