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BILL ANALYSIS

Senate Fiscal Agency

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Senate Bill 69 (Substitute S-1)
Sponsor: Senator Vern Ehlers
Committee: Health Policy

Date Completed: 3-14-89

SUMMARY OF SENATE BILL 69 (Substitute S-1):

The bill 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". The bill also would require the Department of Public Health to promulgate rules to implement these provisions.

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 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).

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

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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 a double-door entry in the clinical lab 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 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 autoclaved before disposal; and, infectious waste that had been autoclaved could be disposed of in a disposal area that was a sanitary landfill approved by the DNR under the Solid Waste Management Act.

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 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 through an appropriate plumbing fixture into a sanitary sewer; infectious waste other than that previously described could be disposed through incineration or in a disposal area that was 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 and if the waste had been decontaminated in this way, the health facility could dispose of it in a sanitary landfill approved by the DNR under the Solid Waste Management Act; 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 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, or disposed of in a sanitary landfill approved by the DNR under the Solid Waste Management Act. 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.

Legislative Analyst: L. Arasim

FISCAL IMPACT

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

Fiscal Analyst: P. Graham

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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.