

MEDICAL WASTE REGULATION: TRAUMA SCENE WASTE MANAGEMENT PRACTITIONERS

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House Bills 4458 & 4459 as introduced

Sponsor: Rep. Fred Miller

Committee: Regulatory Reform

First Analysis (4-30-09)

BRIEF SUMMARY: House Bill 4458 would require trauma scene waste management practitioners to register with the Department of Energy, Labor, and Economic Growth (DELEG); establish registration and renewal fees; and prescribe various duties of a practitioner and the department. House Bill 4459 would make numerous revisions to the code pertaining to producers of medical waste.

FISCAL IMPACT: The bills would have cost implications for the state and local units of government. A detailed discussion of each bill follows later in the analysis.

THE APPARENT PROBLEM:

According to representatives of the Department of Environmental Quality (DEQ), a stakeholder workgroup has worked for several years on developing amendments to the medical waste regulation act within the Public Health Code. Apparently, the act is in need of updating to reflect how the MWRA is currently administered (an executive order several years ago issued by then-Governor John Engler changed the responsibilities assigned to the DEQ), and also to acknowledge and accommodate changes within the industry regarding the generation, management, and treatment of medical waste.

In a related matter, some feel that individuals and companies who clean up medical waste sites resulting from accidents, crimes, and suicides should be regulated by the Department of Energy, Labor, and Economic Growth (DELEG) instead of the DEQ. Supporters of the proposal believe that since DELEG regulates many occupations under the Occupational Code, the department would be well suited to also regulate companies, such as carpet cleaners, who offer their services to crime or accident victims or surviving family members. Reportedly, since many who promote themselves as providing trauma site cleanup do not register as they should with the DEQ under the MWRA, they are flying under the radar, so to speak, and are therefore not disposing of the wastes from the trauma sites in a safe and hygienic manner. For instance, there are reports of trauma cleanup providers disposing of a bloody mattress from a suicide in a dumpster behind a retail store, throwing out bloody carpet or body parts in the regular trash, and washing large amounts of blood into storm sewers with garden hoses. All of these practices are unsanitary, unlawful, and endanger the public health. However, the proposal is not without controversy. Opponents would argue that the DEQ, and not the DELEG, is better suited to regulate this industry, as they are the department with the knowledge and

training to regulate the proper transfer and disposal of materials classified as medical waste.

Separate legislation has been offered to address these concerns – one bill would update the MWRA, and the other would carve out the regulation of those who clean up trauma sites from the DEQ and place it under the purview of the DELEG.

THE CONTENT OF THE BILLS:

Together, the bills would amend Part 138 of Article 12 of the Public Health Code, which is entitled "Medical Waste," in order to:

- Establish a system of registration for trauma scene waste management practitioners.
- Transfer regulatory duties for medical waste producing facilities to the Department of Environmental Quality.
- Establish registration fees.
- Change administrative fines for certain violations to civil fines; provide for injunctive relief; and create a criminal penalty for violations of the act.

The bills are tie-barred, meaning that neither can take effect unless both are enacted. Highlights of each bill follow.

House Bill 4458

The bill would amend the code (MCL 333.1104 and 333.13815) to require trauma scene waste management practitioners to register with the Department of Energy, Labor, and Economic Growth (DELEG); establish registration and renewal fees; and prescribe various duties of a practitioner and the department.

In brief, the bill would do the following:

- For the purposes of Section 13815, specify that the term “department” would mean the Department of Energy, Labor, and Economic Growth.
- Require a person to register with the DELEG before operating as a trauma scene waste management practitioner.
- Allow a person who was previously engaged in such activities prior to the bill's enactment to continue to operate as a trauma scene waste management practitioner if he or she notified the department of the intent to continue operating as a practitioner within 30 days of the bill's effective date and submitted an application for registration by the date prescribed by the department. If the application were denied, the person would have to cease operating as a practitioner, but the person could reapply for registration.
- Require applicants for a registration or a renewal of a registration to submit a registration fee of \$75; a written trauma scene waste management plan as specified in the bill; proof of financial responsibility for injury to another person, property

damage, or environmental damage arising from the trauma scene waste cleanup and transport activities of the practitioner; and a fee to cover a required background check. Fees collected under the bill would be forwarded to the state treasurer for deposit in the Medical Waste Emergency Response Fund.

- Require a background check of all owners, partners, officers, and key employees. If, based on information received from the background check, the request was denied, DELEG would have to provide the reasons for the denial. The person could reapply under the bill's provisions for the new registration category.
- A certificate of registration would be valid for three years.
- DELEG would have to establish standards within 90 days of the bill's effective date (and on a continuing basis), in consultation with the trauma scene waste management industry and the health care industry, requiring documentation of personal protection to be provided and worn by employees; appropriate technologies and chemicals used at the scene; procedures and equipment appropriate for removing, storing, transporting, and disposing of trauma scene waste; and other necessary standards.
- Require each practitioner to develop a trauma scene waste management plan describing how the above standards would be implemented and require compliance with the plan. The plan would have to be updated every year or within 30 days of a change in a person or site named in the plan or a change in the types of trauma scene waste handled or the methods of handling trauma scene waste.
- Require transport of trauma scene waste to a producing facility that decontaminates or incinerates medical waste for treatment or disposal and prohibit storage of trauma scene waste by a practitioner on his or her premises for more than 7 days.
- Allow DELEG to do routine or unannounced inspections to determine whether a trauma scene waste management practitioner should be registered or to investigate complaints. A registration could be denied, suspended, or revoked upon a determination the practitioner cannot engage in the cleanup or transport of trauma scene waste in a manner that would protect the public health, safety, and welfare and the environment. A notice and opportunity for a contested case hearing would be provided before a suspension or revocation.
- Exempt practitioners from the requirements of Sections 13813 and 13817 (both of which would be amended by House Bill 4459), except that a practitioner would have to make the trauma scene waste management plan available to the department upon request. (Failure to do so would subject the person to a civil fine under HB 4459).
- DELEG would have to post and maintain on its website a current list of registered trauma scene waste management practitioners. A person would be provided with a current list of practitioners upon request.
- A provision relating to the registration fee for a producing facility would be eliminated.

House Bill 4459

The bill would make numerous revisions to the code pertaining to producers of medical waste (MCL 333.13805 et al.). Among the significant revisions, the bill would do the following:

- Remove references to the Interdepartmental Medical Waste Advisory Council and place all regulatory responsibilities with the Department of Environmental Quality (DEQ), including administration of the Medical Waste Emergency Response Fund.
- Add definitions of several terms and revise several current definitions; for example, by including "trauma scene waste" in the definition of "medical waste".
- Include transfer stations where medical waste is stored and a trauma waste management practitioner in the definition of a "producing facility" and therefore subject to the act's requirements. Exclude from that term a funeral home that does not embalm or generate medical waste; a home health agency; a residence; a farm operation or other agricultural business; and a facility licensed by the Department of Human Services that provides residential care services.
- Include physician assistants and acupuncturists in determining the size of a producing facility for registration fee purposes; require producing facilities that are not health facilities, such as tattoo and body art facilities, blood draw stations, pharmacies, and others to register and pay a fee; specify a fee for other categories such as a hospital, health facility, or clinical lab.
- Require labeling of containers of medical waste that will be transported to be carried out in compliance with U.S. Department of Transportation regulations. The transport of materials would have to comply with applicable USDOT hazardous material regulations.
- Revise storage requirements and prohibitions, for example prohibit the storing of transfer station storage containers for more than 7 days without approval of the DEQ.
- Require medical waste to be sorted and separated by type and appropriately labeled. Sharps would have to be separated and disposed of as specified in the bill.
- Require review and approval by the DEQ of all non-department approved medical waste treatment technology before installation or use.
- Require a producing facility to have a medical waste management plan on the premises within 90 days of registering with the DEQ and update the plan at least every three years or within 30 days of certain changes listed in the act.
- Allow DEQ to expend money from the Medical Waste Emergency Response Fund for programs relating to medical waste reduction, management, and education, in addition to current restrictions on fund expenditures.

- Allow DEQ to enter at any reasonable time upon private or public property upon which medical waste is reasonably believed to be located in order to determine compliance with Part 138 or rules promulgated under it.
- Allow DEQ to request the attorney general to bring an action for appropriate relief for violations of Part 138.
- Change current administrative fines to civil fines with civil fines of not more than \$2,500 for each violation and an additional civil fine of not more than \$1,000 for each day the violation continues; and a civil fine of \$500 for failure to register as a producing facility or trauma waste management practitioner or to make available to the DEQ the required medical waste management plan. Fine revenue would be deposited in the state's General Fund.
- Allow a court to order a person who violated Part 138 to pay additional costs, including the cost to contain and remove medical waste and the full value of damage done to the state's natural resources. Revenue collected under this provision would be deposited in the Medical Waste Emergency Fund. (However, if a local unit of government incurred the cleanup costs, the court could order the payment be forwarded to that local unit).
- In addition to the costs described above, a person who violated Part 138, a departmental rule promulgated under this part, or a final order would be guilty of a misdemeanor punishable by not more than six months imprisonment and/or a fine of not more than \$1,000.
- Allow the DEQ to issue cease and desist orders to correct a violation.

BACKGROUND INFORMATION:

The bills are similar to House Bills 5574 and 5575 of 2007-08 that were passed by the House but died on the Senate floor.

FISCAL INFORMATION:

House Bill 4458

House Bill 4458 imposes a \$75 three-year fee on trauma scene clean-up firms, which would be licensed by the Department of Energy, Labor, and Economic Growth. It is anticipated that there would be very few firms registering with DELEG and, as such triennial revenue generated from the license fee would be immaterial, likely less than \$1,000. The bill also requires a "background check" on a firm's officers and other "key employees," with the cost of the check borne by the firm. The bill does not specify the type of check, whether it's a simply Michigan criminal history (ICHAT) check, the cost of which is generally \$10 (although free for government agencies) or a fingerprint check, the cost of which is \$54.

Any revenue generated from the licensure fee would be credited to the existing Medical Waste Emergency Response Fund. It's not immediately clear whether funds could be expended by DELEG to support its regulation of trauma scene clean-up firms as required under the bill. House Bill 4459, to which HB 4458 is tie-barred, provides that the Fund could be used by the Department of Environmental Quality for administration and enforcement of the Medical Waste Regulatory Act (Part 138 of the Public Health Code), for remediation of environmental releases of medical waste, and for activities relating to the reduction and management of medical waste. The act, as amended by HB 4459, does not explicitly state that funds could be expended by DELEG to carry out its additional regulatory responsibilities under HB 4458.

To the extent that funds could be utilized by DELEG, it would reduce the available resources to the DEQ for its required activities under the act. In any event, the registration fee revenue, alone, would not sufficiently defray the additional costs imposed on DELEG under HB 4458. The department would incur costs related to its review and processing of applications, the development (and periodic review) of operating standards for trauma scene clean-up firms, enforcement activities, periodic inspection of trauma scene clean-up firms, conducting contested case hearings, and maintenance of the department website. The cost of these activities is, at present, indeterminate, although such costs would not be immaterial. The direct costs of processing applications and conducting inspections and contested case hearings would, in part, depend on the number of firms licensed under the bill. (Again, it is expected few firms would be licensed.).

The costs of developing standards would be independent of the number of firms licensed. In developing these standards the department could, to some extent, incorporate applicable medical waste management standards and procedures developed by the Department of Environmental Quality as well as applicable occupational health standards developed by the Michigan Occupational Safety and Health Administration (see, for example, Part 554 Bloodborne Infectious Diseases). Given the overlapping jurisdictions of DELEG and DEQ, DELEG could also coordinate its enforcement activities with the DEQ, which would continue to have primary oversight over the disposal and management of medical and pathological waste, which would include trauma scene waste under the act, as amended by HB 4459.

House Bill 4459

This bill would not increase program workloads or appropriation requirements for the Department of Environmental Quality. There may be a fiscal impact on local governments, but fund revenue is available for enforcement costs related to regulatory responsibilities and to pay for cost recovery provisions in the bill.

Approximately \$200,000 in revenue is credited each year to the Medical Waste Emergency Response Fund. Spending from this fund in FY 2008-09 is estimated to be \$280,000. A fund balance of \$530,000 was recorded at the end of the last fiscal year (September 30, 2008).

There would be an indeterminate fiscal impact on the judiciary as a result of this bill. The courts would likely realize an increase in administrative costs from the collection and transfer of civil fine and cost revenue. The civil fine revenue would be deposited in the General Fund; revenue from the additional costs the court may order for containment and removal of the wastes as well as for the damage done to natural resources would be deposited into the Medical Waste Emergency Fund. If the local unit of government incurred clean up costs, the court could order that the cost revenue be forwarded to the local unit of government.

Local public health departments may incur additional costs under the bill related to compliance inspections for body art facilities which are required annually for state licensure, enacted in December 2007. Compliance inspections by local health departments will now need to recognize requirements of the Medical Waste Regulatory Act. Local health departments may charge a fee for the costs of these compliance inspections under current state law.

To the extent that misdemeanor convictions increased under the bill, local units of government could experience increased costs of misdemeanor sanctions, including misdemeanor probation supervision and incarceration in the county jail, both of which vary with jurisdiction. Any increase in penal fine revenue could benefit local libraries, which are the constitutionally-designated recipients of such revenue.

ARGUMENTS:

For:

House Bill 4459 would make necessary changes to the medical waste regulatory act within the Public Health Code. Among other things, the bill would clarify that body art facilities are medical waste producers and that in addition to being licensed under the Public Health Code, must also register with the DEQ under the MWRA. This is similar to physicians, dentists, and other professionals who, in the course of their practice, generate medical waste.

Further, the bill incorporates most of the recommendations generated by a workgroup of industry stakeholders that will bring the act up to date regarding changes in technology and how medical waste is generated, transported, and properly managed (e.g., safe disposal).

Response:

The DEQ has identified several amendments of a technical nature that it would like to see added. For instance, the term "residence" should be changed back to "household," as is currently the case in the MWRA. Whereas "residence" is not defined, "household" is and so could be confusing and misleading. Most importantly, the department is requesting that the tie-bar to House Bill 4458 be removed.

For:

Apparently, a wide array of state and out-of-state individuals and companies promote themselves as providing clean up for trauma sites, such as accidents, crime scenes, and

suicides. Under current law, the MWRA, these persons are treated the same as producers of medical wastes such as hospitals. In practice, the trauma scene cleanup may be provided by a carpet cleaner who monitors a police radio scanner and moves in after the police leave. Reportedly, most of these people are not registered with the DEQ, don't know that they should be, the DEQ are not aware of them, and they are not properly disposing of or transporting the medical wastes generated by the trauma scene cleanup. Moreover, there are reports that some of these people demand excessively high payments up front and engage in threatening or abusive practices if not paid as demanded.

The bill would address these issues by carving out the regulation of these businesses from the DEQ and placing them under the regulatory eye of the DELEG. DELEG regulates many occupations, and so is better suited to provide oversight ensuring that those providing trauma waste scene cleanup are registered, trained, and following the proper standards in the cleanup.

Against:

Carving out regulation of trauma scene waste management practitioners from the DEQ to the DELEG, as House Bill 4458 would do, will not solve the problems supporters believe it will. For starters, DELEG is already overburdened with regulatory duties it cannot keep up with. For example, there is a backlog of several years of complaints for the building trades alone that the department does not have adequate staffing to address. And, enforcing proper disposal of materials used in the building trades and other professions currently regulated by DELEG is very different from providing necessary oversight of medical wastes. All of the medical professionals, the major generators of medical wastes, are regulated under the Public Health Code, with DEQ for years managing those issues that affect the environment, such as hazardous wastes of all kinds.

Indeed, carving out those who clean up trauma scenes from DEQ's oversight could be more costly and problematic. For instance, they would be the only handler of medical wastes required to be bonded and undergo criminal background checks. (It is not clear if the criminal check would be a name check only, insufficient if for an out-of-state practitioner or a person using a fraudulent identity, or a fingerprint check which is costly and time-consuming). It also requires DELEG to recreate the wheel, so to speak, to consult with industry experts and develop proper standards for the management of the waste products from trauma scene wastes – something that is well established with the DEQ.

Most disconcerting is that House Bill 4458 takes away from the department which has the expertise to identify hazardous waste and when it is not being handled properly the ability to regulate and punish trauma scene waste practitioners and gives those responsibilities to an agency without the scientific and medical training to make such judgments.

The irresponsible practices on the part of those promoting themselves as able to clean up trauma scenes can be addressed by educating law enforcement personnel, prosecutors, medical examiners, local code enforcement agencies, and the public as to the training and registration requirements of the law. Perhaps DEQ could provide a list of registered

trauma scene waste management companies on its website. Such actions would go further to ensure the proper registration of these practitioners and the use of registered professionals by the public than the program House Bill 4458 would create.

POSITIONS:

The Department of Environmental Quality supports House Bill 4459, opposes House Bill 4458, and requests the tie-bar be broken. (3-4-09)

A representative of Elite Trauma Clean-Up, Inc. testified in support of the bills. (3-4-09)

The Michigan Society for Infection Prevention and Control supports House Bill 4459, but opposes House Bill 4458 and the tie-bar. (3-4-09)

The Association for Professionals in Infection Control & Epidemiology, Inc./Greater Detroit support House Bill 4459, but oppose House Bill 4458 and the tie-bar. (3-04-09)

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