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LANSING



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VIA E-MAIL

TO: Governor Rick Snyder  
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Senate Health Policy Committee Members  
House Natural Resources Committee Members  
House Health Policy Committee Members  
Nick Lyon, Director, Department of Health and Human Services

FROM: C. Heidi Grether, Director *CHG*

DATE: October 13, 2016

SUBJECT: Report on the 2015 Medical Waste Regulatory Program

In accordance with Section 13827(3)(b) of the Medical Waste Regulatory Act (MWRA), Part 138 of the Public Health Code, 1978 PA 368, as amended, attached is the Department of Environmental Quality's (DEQ) report on the Medical Waste Regulatory Program for fiscal year 2015.

Various types of facilities in Michigan, including hospitals, dental offices, funeral homes, body art facilities, and many others, generate regulated medical waste. The primary function of the MWRA and the program is to safeguard public health and the environment from exposure to potential hazards resulting from the improper handling, storage, treatment, and/or disposal of regulated medical waste. In addition to an introduction and brief history of the MWRA and the program, this annual report includes information regarding funding and operation of the program, current initiatives, program developments, registrant statistics, and incident summaries.

If you need further information, please contact Steve Sliver, Acting Chief, Office of Waste Management and Radiological Protection, at 517-284-6551; or you may contact me at 517-284-6700.

Attachment

Report on the 2015 Medical Waste Regulatory Program

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cc/att: Ellen Jeffries, Director, Senate Fiscal Agency  
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**2015  
ANNUAL REPORT**

**Medical Waste Regulatory Program**



Prepared for the Governor, the standing committees in the Senate and the House of Representatives with jurisdiction over public health matters, and the Department of Health and Human Services, as required by the Medical Waste Regulatory Act, Part 138 of the Public Health Code, 1978 PA 368, as amended.

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October 13, 2016

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## I. INTRODUCTION

The Medical Waste Regulatory Act (MWRA), Part 138 of the Public Health Code, 1978 PA 368, as amended, enacted in 1990, authorizes State regulatory oversight of medical waste producing facilities. Section 13827(3)(b) of the MWRA requires that an annual report be submitted to the Governor, the standing committees in the Senate and the House of Representatives with jurisdiction over public health matters, and the Department of Health and Human Services (DHHS).

Staff of the Department of Environmental Quality (DEQ), Office of Waste Management and Radiological Protection (OWMRP), Medical Waste Regulatory Program (MWRP), prepared this report for the period of October 1, 2014, to September 30, 2015, fiscal year (FY) 2015.<sup>1</sup>

The purpose of the MWRA is to safeguard public health by preventing human exposure to physical injury or contraction of communicable diseases, which may result from the improper management of potentially infectious medical waste. The regulations also serve to protect Michigan's environment and natural resources from degradation.

The enactment, administration, and enforcement of the MWRA and subsequent promulgation of its administrative rules have resulted in significant benefits to Michigan's citizens and the environment. Some notable benefits include:

- Continued reduction in medical waste mismanagement and improper disposal incidents, decreasing the potential for exposure risks to the public and degradation of Michigan's environment.
- Increased understanding of current and emerging medical waste issues within the regulated community and improved awareness of related waste disposal issues. These include the proper handling and disposal of personal care products, pharmaceuticals, and dental amalgam waste containing mercury and establishment of more voluntary programs offering collection and proper disposal of home-generated sharps waste (primarily from diabetics).
- Strengthened ties to the regulated community and education of its members on medical waste concerns through outreach, online reference materials, participation on advisory work groups, and delivery of training and presentations.
- Increased compliance with medical waste regulations and better tracking and handling protocols through the MWRP's education, compliance assessment, and enforcement when necessary. This has improved through continuous quality improvement efforts, such as identification and notification of facilities that are out of compliance, partnering with local health departments to promote educational outreach, and offering improved online accessibility to the regulated community to increase customer satisfaction and overall program efficiency.

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<sup>1</sup> The Interdepartmental Medical Waste Advisory Council, as described in Section 13827, was eliminated by Executive Order No. 2009-28, effective July 31, 2009. Responsibility for the completion and submission of annual reports, as required under the MWRA, was assigned to MWRP staff by the DEQ, Executive Division.

- Increased use of effective, safe, and environmentally sound treatment alternatives to incinerating medical waste through the approval of new technologies. MWRP staff coordinates with a diverse group of professionals representing both interdepartmental and intradepartmental programs to perform timely and thorough reviews of new technologies to ensure the devices are in compliance with all applicable rules and regulations.

## **II. MWRA AND PROGRAM HISTORY**

The Legislature enacted the MWRA in response to incidents of medical waste washing ashore on the beaches of Lake Erie and Lake Michigan in 1989. Early administration of the MWRA focused on the identification and registration of all medical waste producers, investigations of reported violations of the MWRA, and enforcement of the statute. In 1998 staff also began providing education and training to producing facilities. The administrative rules pursuant to the MWRA were adopted in 2000.

In November 2001 Executive Order 2001-9 transferred the balance of the restricted Medical Waste Emergency Response Fund to Michigan's General Fund to help address the State's budget deficit. The MWRP was dissolved in FY 2002 for the resulting lack of funding. The enabling statute was not repealed, however, leaving regulatory requirements in place without enforcement. In May 2003 pursuant to Governor Jennifer Granholm's executive directive, the DEQ reestablished the MWRP, assigning one program specialist to administer the MWRA. Registration of producing facilities resumed.

In 2004 a second staff member was hired and assigned to provide increased technical support, assist with routine administrative functions, provide education and assistance to the regulated community, and assist with complaint response and general compliance-based audits of medical waste producing facilities.

In January 2011 the existing program specialist retired and was not replaced. The remaining professional staff person now serves as the program specialist. A registration technician has since been assigned on a part-time basis to assist with processing medical waste registrations and issuing registration certificates to regulated facilities as required by the MWRA.

## **III. PROGRAM FUNDING**

The MWRP is funded through registration fees collected from medical waste producing facilities. No General Fund money is allocated to the program to administer the MWRA. Funds received are statutorily restricted and deposited into the Medical Waste Emergency Response Fund as required by the MWRA. The current statute allows for the use of these funds for administration of core MWRP functions and regulations, including contracted field inspection activities performed by local health departments (LHD), investigation of reported allegations/incidents, remediation actions to have the waste properly removed and treated for disposal, and costs due to the improper release of medical waste into the environment.

Registration fees are set by the statute and vary by facility type. The fees range from \$50 to \$150 depending on the facility type. Registrations are valid for a three-year period and renewable under the same fee structure. It is estimated that nearly 70 percent of registrants are small private practices that do not pay in excess of \$50 every 3 years, or about \$17 annually on average. The remaining 30 percent of registrants, including large

hospitals, other medical/research facilities, and some non-medical based facilities (tattoo/body art, medical waste disposal facilities, etc.), submit registration fees of \$75-\$150 based upon their facility type and, therefore, do not pay in excess of \$50 on an annual basis during the three-year cycle. Registration fees have not increased since adoption of the original statute in 1990.

Registration fees generate an average of \$291,000 in revenue each year. This level of funding limits the MWRP to processing registrations, responding to complaints, and providing technical assistance to the regulated community and public. Current funding does not support routine inspections and compliance assistance at the more than 15,000 producers of medical waste.

The Office of the Auditor General's performance audit of the MWRP from October 1, 2012, through September 20, 2015, found that the current fees are not adequate to support recommended inspections of medical waste producers.

To address this and other findings, the MWRP is working to convene a Medical Waste Stakeholder Advisory Group (MWSAG) to conduct a comprehensive review of the MWRA related to furthering the DEQ's ability to administer a comprehensive, relevant program. As part of their charge, the MWSAG will be asked to evaluate the pilot inspection grant program and the potential for its expansion to additional local health departments. If the MWSAG recommends amending the MWRA to improve safeguards to public health and program administration, then MWRP staff and OWMRP management will work with members of the MWSAG to develop stakeholder-approved statute amendments to the MWRA.

#### **IV. PROGRAM ADMINISTRATION**

Despite the challenges resulting from funding limitations as described in Section III, the MWRP continues to focus on the creation and implementation of quality improvement efforts to assist the regulated community and efficiently administer the requirements of the MWRA by making the best use of existing resources. Administrative functions include processing registrations and providing compliance assistance to medical waste producing facilities. The MWRP also responds to reports of improper management and releases of medical waste into the environment.

Staff undertook the following noteworthy activities in FY 2015:

- Continued collaborative efforts working with the Department of Technology, Management and Budget to make further improvements to the License 2000 (L2K) database, which is used to store non-sensitive registrant data. This database is used by the DEQ, the Department of Licensing and Regulatory Affairs (DLARA), the DHHS, and other state departments that administer a variety of licensing and registration programs. A major objective was successfully completed and implemented at the end of FY 2015, allowing for all medical waste producers to have full online capabilities in renewing or obtaining new registrations. In addition, the MWRP has provided easy online access to useful reference information and continues to strive to provide excellent customer service to program customers.
- Improved compliance assistance and educational outreach through networking and partnerships with local health departments and professional organizations. An ongoing

pilot program launched in collaboration with nine LHDs representing 23 of Michigan's counties was continued through a grant contract agreement to promote compliance assistance and educational outreach to regulated facilities in FY 2015. As a result, over 650 facilities were visited during the fiscal year, and a comprehensive evaluation of the pilot program supports the continuation and expansion of the program if resources are available.

- Performed individual field training on how to execute compliance outreach and inspection activities for large volume producers and unregistered facilities for 22 LHD staff inspectors, focusing on the requirements of the MWRA, utilization of reference materials and referral information, and inspection protocols. The inspector training was conducted at medical waste producers in each of their respective jurisdictions.
- Investigated all received reports of alleged improper medical waste treatment and/or disposal. The program started in FY 1991, and at that time staff received and investigated 120+ complaints of improper disposal during that year. As of FY 2015, only 3 incidents were reported and investigated, demonstrating over a 97 percent decrease in reported incidents of violations of the MWRA since inception.
- Continued to distribute a simple but comprehensive "Pocket Guide" reference to assist the regulated community and expand awareness of the MWRP and its purpose. Distribution of the guide was facilitated by networking with LHD inspectors and DLARA's Radiation Safety Section field staff at facilities throughout Michigan.
- Updated and added several new online reference and compliance assistance materials on the MWRP Web site to provide expanded information regarding MWRP requirements, compliance assistance services, educational reference materials, and links to related state and federal programs.
- Recruited and provided assistance to hospitals, private medical practices, and LHDs in an ongoing effort to expand the number of home-generated medical sharps collection services for residents of each of Michigan's 83 counties. Staff routinely updated and maintained the listing on the MWRP Web site and demonstrated success in recruiting several additional residential sharps collection programs in FY 2015. This is an ongoing effort.

## **V. CURRENT INITIATIVES**

In addition to the ongoing core functions, MWRP staff have undertaken the following key initiatives in FY 2016:

- Implementation of the third phase of pilot project activities with nine LHDs for inspections of various medical waste producers, identification and registration of unregistered facilities, provision of educational presentations to the industry and/or the public, and recruitment of volunteer sharps collection programs. In the past two fiscal years, such activities have resulted in positive educational outreach and compliance assistance as conveyed by both participating LHD staff and the regulated community.
- The pilot program continues into FY 2016 and is being completed as in previous years as described below:

- Facility inspections continue under a grant contract agreement with nine of Michigan's LHDs, to promote a "compliance assistance" approach in providing educational outreach to registrants in lieu of using a traditional, punitive regulatory audit approach. Drawing from feedback provided in follow up to the FY 2014 and FY 2015 pilot inspection program, LHD inspectors and members of the medical waste producing community commented that utilizing an educational outreach/compliance assistance approach to inspection activities made registrants more agreeable to inspection and more comfortable with asking for assistance, made the inspection interactions less adversarial, and resulted in a more positive view of state and local government inspection activities and why they are important.
- In response to an FY 2015 audit of the MWRP, which noted a lack of follow-up inspections at facilities where violations were observed, activities include follow up with facilities visited in prior years to ensure they have adequately addressed any noted violations.
- Notification to unregistered medical waste producing facilities about MWRA compliance requirements and the ability to complete online registration. The identification and notification of unregistered facilities was made possible via assistance from the DLARA's Bureau of Health Professions, the DHHS's tattoo/body art licensing program, and the DLARA's Radiation Safety Section. The comparison of the MWRP registrant database with these other databases resulted in the identification of a large number of facilities that require registrations per the MWRA.
- Continue to increase the number of voluntary public sharps collection programs around the state. This is an ongoing effort by the MWRP to identify, recruit, and maintain residential collection programs in each of Michigan's 83 counties.
- Continue to improve the quality of registrant data in the L2K database and, by working with DLARA, pursue further enhancements of the online functionality of the system. Enhanced functionality that allows initial (new) registrants to register online is key to excellent customer service and will reduce administrative burdens of the MWRP.
- Continue to assist the DHHS in the development of tattoo and body art facility licensing and inspection rules under the Body Art Facilities Act, 2010 PA 375. The proposed rules, once completed, will be presented for consideration by Department of Technology, Management and Budget's Office of Regulatory Reinvention in accordance with their administrative rule promulgation procedures.
- Convene a diverse group of stakeholder's to continue efforts aimed at evaluating the MWRA regulations, including the funding structure, and follow up on recommendations as described in Section VI of this document.

## **VI. PENDING LEGISLATIVE DEVELOPMENTS**

In an effort to increase compliance with the MWRA, improve the effectiveness of the MWRP, and promote excellent customer service to the public and the regulated community, the DEQ intends to consult with stakeholders to conduct a comprehensive evaluation of the MWRA and previously recommended amendments to the MWRA that would do the following:

- Correct outdated language and add new definitions to better reflect changes in the regulated industry that have occurred since the enactment of the statute in 1990.
- Establish testing requirements to verify continual effective and efficient operation of decontamination equipment used for treating medical waste before final disposal of the waste.
- Update the definition of medical waste producers to specify all professions that are subject to the requirements. Examples include physician assistants, acupuncturists, tattoo/body artists, and trauma scene cleanup professionals.
- Propose a fee structure that allows for expansion of LHD inspection activities that have been performed as part of the MWRP's pilot project.
- Enable DEQ staff to certify and contract with LHDs to perform field activities that promote compliance assistance, awareness, and educational outreach.

## VII. ACTIVE REGISTRANTS BY FACILITY TYPE

Facility Type	Active Registrants FY 2015
Private Practice Medical, Dental, and Veterinary Facilities	10,123
Clinics (e.g., LHDs and Universities)	530
Funeral Homes/Mortuaries	487
Nursing Homes, Hospices, County Medical Care Facilities, and Health Maintenance Organizations	538
Clinical, Analytical, and Research Laboratories	126
Hospitals	184
Freestanding Surgical Outpatient Facilities	102
Mental Health Facilities	129
Ambulance/Paramedic/Fire Departments	106
Animal Control Shelters	2
Pharmacies	1,399
Other (e.g., Dialysis, Blood Collection, Medical Education, and Body Art)	1,779
State Facilities	49
<b>Current Active Registrations</b>	<b>15,554</b>

Source of Information: *Medical Waste Program Database, April 2016*

**VIII. SUMMARY OF MEDICAL WASTE MANAGEMENT INCIDENT REPORTS BY LOCATION, TYPE, AND DATE [October 1, 2014 - September 30, 2015]**

**Wayne County, Michigan – October 2013 to May 2015**

Stemming from an ongoing incident that began in FY 2014 and continued into FY 2015, the DEQ continued to investigate a large-scale operation storing a significant volume of medical waste in excess of 90 days at a self-storage facility in Detroit.

The investigation required significant effort by multiple department staff, local law enforcement, and federal officials and was remediated/closed in FY 2015.

**Oakland County – August 2015**

MWRP staff received a complaint alleging possible improper disposal of regulated medical waste at a medical clinic. Staff investigated and determined the complaint was unfounded, although several administrative violations of the MWRA were noted. The facility corrected these violations as requested and was determined to be returned to compliance with the MWRA. Complaint closed.

**Oceana County – September 2015**

A report was received by the MWRP indicating that several used hypodermic needles were found washed up on the beach of Lake Michigan near a series of vacation rental properties in Oceana County. A field investigation was performed by MWRP staff and the area was meticulously surveyed for these items. Due to strong waves and a significant storm that had occurred the previous day, staff was unable to locate any used needles. It was determined that, due to weather conditions, the waste may have moved out into the water or had been covered with sand from strong winds. Alternatively, the alleged needles could have been cleaned up by someone. MWRP staff considered this to be the result of an isolated incident. Complaint closed.