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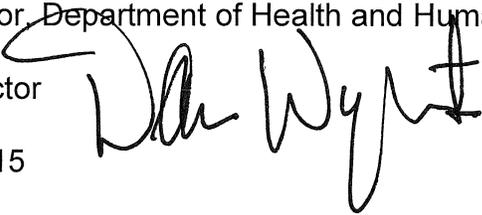
STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING



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DIRECTOR

VIA E-MAIL

TO: Governor Rick Snyder
Senate Natural Resources Committee Members
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: Dan Wyant, Director 

DATE: September 2, 2015

SUBJECT: Report on the 2014 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 2014.

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 Bryce Feighner, P.E., 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 2014 Medical Waste Regulatory Program

Page 2

September 2, 2015

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**2014
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 Part 138, Medical Waste Regulatory Act, of the Public Health Code, 1978 PA 368, as amended.

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September 2, 2015

TABLE OF CONTENTS

| | | |
|-------|---|-----------|
| I. | Introduction | page 1 |
| II. | MWRA and Program History | page 2 |
| III. | Program Funding | page 2 |
| IV. | Program Administration..... | pages 2-3 |
| V. | Current Initiatives | pages 3-4 |
| VI. | Pending Legislative Developments..... | page 5 |
| VII. | Active Registrants at Close of FY 2013 vs. Active Registrants at Close of FY 2014..... | page 6 |
| VIII. | Summary of Medical Waste Management Incident Reports..... | page 7 |

I. INTRODUCTION

The Medical Waste Regulatory Act (MWRA), Part 138 of the Public Health Code, 1978 PA 368, as amended (Public Health Code), 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, Medical Waste Regulatory Program (MWRP), prepared this report for the period of October 1, 2013, to September 30, 2014, fiscal year (FY) 2014.¹

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:

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

¹ 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.

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 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. 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. Funds are deposited into the restricted Medical Waste Emergency Response Fund. The MWRA authorizes up to 80 percent of revenue to this Fund to be used for administration of the MWRP. The remaining revenue may be used to respond to the release of medical waste into the environment.

The registration fee varies by facility type from \$50 to \$150, and the registrations are valid for a three-year period. Registration fees generate an average of \$291,000 in revenue each year. Fees have not increased since adoption of the original statute in 1990.

IV. PROGRAM ADMINISTRATION

The MWRP focuses on continuous quality improvement to assist the regulated community and efficiently administer the requirements of the MWRA. 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.

In addition to the core functions, the MWRP staff continues to pursue process improvements that will make the MWRP more efficient and effective. Staff undertook the following noteworthy activities in FY 2014:

- Initiated ongoing collaborative efforts with the Department of Technology, Management and Budget to make further improvements to the L2K database used by the DEQ, the Department of Licensing and Regulatory Affairs (DLARA), and other departments that administer a variety of licensing and registration programs. The goal for all regulated

entities to have full online capabilities in renewing or obtaining new registrations, having easy access to useful reference information, and being provided with excellent customer service are ongoing efforts.

- Improved compliance assistance and educational outreach through networking and partnerships with local health departments and professional organizations. A pilot program launched in collaboration with 9 local health departments (LHD) representing 23 of Michigan's counties was initiated to promote compliance assistance and educational outreach to regulated facilities in FY 2014. Over 650 facilities were visited during the fiscal year, and a comprehensive evaluation supported the continuation of further activities moving into FY 2015.
- 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 2014, only 1 incident was reported and investigated, demonstrating over a 99 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. Distribution of the guide was facilitated by networking with LHD inspectors and DLARA's Radiation Safety Section field staff at facilities throughout Michigan.
- Provided training to LHD inspectors performing permitting activities in the field of tattoo and body art facilities as required under the Body Art Facilities Act, 2010 PA 375 (Act 375), and participated in the DHHS stakeholder work group process for the development of tattoo and body art facility rules to implement Act 375 to be administered properly by addressing and streamlining overlapping regulations under the DEQ, DHHS, and DLARA.
- MWRP staff worked with owners of medical waste transport and treatment facilities to ensure their clients have a better understanding of state regulations and how to achieve and maintain compliance.
- 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 a total of 20 new residential sharps collection programs in FY 2014. This is an ongoing effort.

V. CURRENT INITIATIVES

In addition to the ongoing core functions, the MWRP staff will undertake the following key initiatives in FY 2015:

- Implement the second phase of pilot project activities with nine LHDs for inspections of large volume medical waste producers and identification and registration of unregistered facilities. These activities have resulted in positive educational outreach and compliance assistance as conveyed by both participating LHD staff and the regulated community.

The pilot program described above, beginning in FY 2014, and continuing into FY 2015, will focus primarily on the following:

- Facility inspections will 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 FY 2014 activities, it has been noted by LHD inspectors and members of the regulated community that by using this approach, registrants are more comfortable asking questions, the interactions are not adversarial in nature, and the regulated entities and staff often develop a more positive view of state and local government activities and why they are important.
- The MWRP program specialist will train approximately 22 LHD staff on the requirements of the MWRA, reference materials and referral information, and inspection protocols and perform on-site field training for inspectors at each of their respective jurisdictions.
- Following the implementation for the capability of new registrations to be completed online, the MWRP intends to notify unregistered facilities in 36 additional LHD jurisdictions concerning registration and compliance requirements. 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 our registrant database with other permitted or licensed medical facilities by the DLARA resulted in the identification of a large volume of facilities that require registrations per the MWRA.
- Continue to increase the number of voluntary public sharps collection programs. This will be done primarily by reaching out to the regulated community, local municipalities, and other organizations to request participation in these programs at the city or county level and has been done this way in the past. This is an ongoing effort by the MWRP to identify, recruit, and maintain residential collection programs in each of Michigan's 83 counties.
- Improve the quality of registrant data in the L2K database and pursue further enhancements of the functionality of the system online. In our mission to provide excellent customer service, the functionality to allow initial (new) registrants to register online is expected to be completed and implemented in FY 2015.
- Continue to assist in the development of tattoo and body art facility licensing and inspection rules under Act 375. The proposed rules, once completed, will be presented for consideration by DLARA's Office of Regulatory Reinvention in accordance with their administrative rule promulgation procedures.

VI. PENDING LEGISLATIVE DEVELOPMENTS

In an effort to increase compliance with the MWRA, improve the effectiveness of the program, and promote excellent customer service to the public and the regulated community, the DEQ intends to consult with stakeholders on potential amendments to the MWRA that do the following:

- Clarify outdated language and add new definitions to better reflect typical operations and 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.
- Enable DEQ staff to certify and contract with LHDs to perform field activities that promote compliance assistance, awareness, and educational outreach.

VII. ACTIVE REGISTRANTS AT CLOSE OF FY 2013 VS. ACTIVE REGISTRANTS AT CLOSE OF FY 2014

| Facility Type | Active Registrants FY 2013 | Active Registrants FY 2014 |
|---|-----------------------------------|-----------------------------------|
| Private Practice Medical, Dental, and Veterinary Facilities | 10,244 | 10,346 |
| Clinics (e.g., LHDs and Universities) | 510 | 516 |
| Funeral Homes and Mortuaries | 501 | 519 |
| Nursing Homes, Hospices, County Medical Care Facilities, and Health Maintenance Organizations | 485 | 486 |
| Clinical, Analytical, and Research Laboratories | 114 | 132 |
| Hospitals | 184 | 182 |
| Freestanding Surgical Outpatient Facilities | 89 | 92 |
| Mental Health Facilities | 124 | 127 |
| Ambulance/Paramedic/Fire Departments | 98 | 125 |
| Animal Control Shelters | 21 | 27 |
| Pharmacies | 1,219 | 1,250 |
| Other (e.g., Dialysis, Blood Collection, Medical Education, and Body Art) | 1,345 | 1,413 |
| State Facilities | 49 | 51 |
| Current Active Registrations | 14,983 | 15,266 |
| Percent Increase in Active Registrations from FY 2013 to FY 2014 | 1.9% | |

Source of Information: *Medical Waste Program Database, 09/30/2014*

VIII. SUMMARY OF MEDICAL WASTE MANAGEMENT INCIDENT REPORTS BY LOCATION, TYPE, AND DATE [October 1, 2013 - September 30, 2014]

Detroit, Michigan – October 2013 to September 2014

Stemming from an ongoing incident that occurred in FY 2013 and continued into FY 2014, the DEQ continued to investigate a large-scale operation storing a very large amount of medical waste in excess of 90 days at a self-storage facility in Detroit.

As background information, in FY 2013 MWRP staff was notified of a large fire in a factory building in Detroit used by the medical waste transporter aforementioned above. The building was subsequently demolished, and most of the remaining medical waste was removed by the transporter to the self-storage facility in four separate large-volume units. Despite letters of violation and enforcement activities being issued to the owner, operations continued and the transporter continued to collect medical waste and store it. The investigation is nearly concluded and expected to be remediated and closed in FY 2015.