

Texas Commission on Environmental Quality

Interoffice Memorandum

To: Commissioners **Date:** April 20, 2016

Thru: Bridget C. Bohac, Chief Clerk
Richard A. Hyde, P.E., Executive Director

From: Brent Wade, Deputy Director
Office of Waste

Docket No.: 2015-1448-RUL

Subject: Commission Approval for Rulemaking Adoption
Chapter 326, Medical Waste Management
Chapter 330, Municipal Solid Waste
Chapter 335, Industrial Solid Waste and Municipal Hazardous Waste
HB 2244: Medical Waste
Rule Project No. 2015-019-326-WS

Background and reason(s) for the rulemaking:

House Bill (HB) 2244 was passed by the 84th Texas Legislature and became effective June 10, 2015. The bill added Texas Health and Safety Code (THSC), §361.0905 to the THSC, Regulation of Medical Waste, requiring the Texas Commission on Environmental Quality (commission or TCEQ) to require a permit, registration, or other authorization for the handling, storage, disposal, and transportation of medical waste. Title 30 Texas Administrative Code (TAC) Chapter 330 implements THSC, Chapter 361, which requires the commission to safeguard the health, welfare, and physical property of the people and to protect the environment by controlling the management of solid waste, including accounting for types of solid wastes such as medical waste. The commission is required to adopt rules implementing THSC, §361.0905 by June 1, 2016.

Scope of the rulemaking:

This rulemaking will amend and repeal portions of 30 TAC Chapters 330 and 335 related to the management of medical waste and create a new 30 TAC Chapter 326 for the handling, transportation, storage, and disposal of medical waste. The legislatively mandated amendments also include making operational changes that apply to medical waste facilities such as buffer zones, and storage in transport vehicles at a facility.

A.) Summary of what the rulemaking will do:

Chapter 330 will be amended to repeal Subchapter Y and transfer contents relating to medical waste management to adopted new Chapter 326. Sections within Chapters 330 and 335 that reference Chapter 330, Subchapter Y will also be revised to reference adopted new Chapter 326.

Chapter 326 will organize the rules from Chapter 330, Subchapter Y by level of authorization. The new chapter will be outlined as follows:

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- Subchapter A, General Information, will establish the purpose and applicability, define terms, establish general prohibitions and specify other authorizations required by other TCEQ programs such as air permitting and water quality permitting.
- Subchapter B, Packaging, Labeling and Shipping Requirements, will establish medical waste labeling and packaging for transport to a treatment or disposal facility. Recordkeeping requirements and provisions for both generators and transporters will also be established.
- Subchapter C, Exempt Medical Waste Operations, will establish exempt facilities from medical waste authorizations. These facilities would be all generators and those small quantity generators that self-transport.
- Subchapter D, Operations Requiring a Notification, will establish the process and requirements for medical waste operations to request a notification authorization. These facilities are on-site treatment facilities and medical waste collection stations.
- Subchapter E, Operations Requiring a Registration by Rule, will establish the process and requirements for transporters and mobile on-site treatment units to operate under a Registration by Rule.
- Subchapter F, Operations Requiring a Registration, will establish registration requirements for facilities that store or process untreated medical waste that is received from off-site sources.
- Subchapter G, Fees and Reporting, will establish fees for solid waste processing for disposal within the state and for registered transporters. It will also establish reporting requirements for stored and processed waste.

B.) Scope required by federal regulations or state statutes:

HB 2244 passed by the 84th Texas Legislature requires revision to commission rules by June 1, 2016. The commission has the powers and duties prescribed by THSC, Chapter 361, Subchapter C, relating to medical waste regulation and all other powers necessary or convenient to carry out responsibilities under that chapter. Rules adopted to regulate the management of municipal solid waste will apply in the same manner to medical waste only to the extent that the rules address:

- (1) permit and registration requirements;
- (2) minor modification for permits and registrations;
- (3) the reconciliations of conflicting site operation plan requirements;
- (4) waste acceptance and analysis;
- (5) facility-generated waste, including wastewater and sludge;

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- (6) contaminated water management;
- (7) on-site storage areas for source-separated or recyclable materials;
- (8) waste storage;
- (9) closure requirements;
- (10) recordkeeping and reporting requirements;
- (11) fire protection;
- (12) access control;
- (13) unloading waste;
- (14) spill prevention and control;
- (15) operating hours;
- (16) facility signage;
- (17) control of litter, including windblown material;
- (18) noise pollution and visual screening;
- (19) capacity overloading and mechanical breakdown;
- (20) sanitation, including employee sanitation facilities;
- (21) ventilation and air pollution control; and
- (22) facility health and safety plans.

In matters relating to medical waste regulation, the commission shall consider water pollution control and water quality aspects, air pollution control and ambient air quality aspects, and the protection of human health and safety.

C.) Additional staff recommendations that are not required by federal rule or state statute:

Revisions to tailor the waste rules for medical waste and remove inapplicable requirements.

Statutory authority:

HB 2244

THSC, §361.0905, Regulation of Medical Waste

Effect on the:

A.) Regulated community:

The rulemaking will reduce the minimum buffer zone required between processing equipment or storage areas and the facility boundary. The regulated community will have a period of two years after the effective date of this rulemaking to revise current registrations and permits without public notice to be in compliance with the new rules. Registrations by Rule will be subject to the new rules upon their annual renewal, and other lower tier authorizations will be subject to the new rules without taking any action.

B.) Public:

None.

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C.) Agency programs:

None.

Stakeholder meetings:

Stakeholder meetings were held August 18, 2015 and September 21, 2015. TCEQ staff presented a general approach to the rulemaking and asked the stakeholders for feedback on some key issues. Stakeholders generally supported the rulemaking and recognized the benefit to the regulated community.

Public comment:

The commission held a public hearing on January 25, 2016, at TCEQ headquarters in Austin. Oral comments were presented by Stericycle, Inc. No other oral comments were presented.

During the public comment period the commission received written comments from Biomedical Waste Solutions, LLC, Cook-Joyce, Inc., Gulfwest Solutions, Sharps Compliance, Inc., Stericycle, Inc., Titanium Environmental Services, and The University of Texas System Environmental Health & Safety Advisory Committee. Significant public comments are summarized as follows.

Biomedical Waste Solutions and Stericycle commented on the new application requirements. Specifically, concerns about submitting a new registration application that would require new engineering seal and signatures. Cook-Joyce requested that entities operate under their existing authorization instead of a two-year deadline to comply with the new rule.

Stericycle commented that operating hour and buffer zone changes should be processed as non-notice modifications.

Several commenters requested removing the continuous refrigeration requirement for transporters that pick up refrigerated waste. Commenters also stated that most route trucks are not refrigerated and this would cause an increased cost for transporters and to healthcare.

Several commenters recommended extending the temporary storage time allowed without a storage registration from 24 to 72 hours to accommodate long distance routes and multiple pickup locations prior to treatment and disposal.

Cook-Joyce, Biomedical Waste Solutions, and Gulfwest Solutions commented on the disposal methods for non-hazardous pharmaceuticals and trace chemotherapy wastes. Gulfwest Solutions supports the proposed disposal method of incineration and provided several references to federal guidance documents which document that incineration is currently the only recommended treatment option for these wastes. Cook-Joyce and

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Biomedical Waste Solutions requested additional options such as autoclaving. Cook-Joyce also commented on past approval of other treatment methods.

Stericycle commented to decrease the distance from within one mile of the facility boundary to adjacent to the facility boundary for land-use and surrounding area impact information.

Stericycle commented that requirements for landfills such as traffic study, noise pollution and visual screening, random inspections for incoming waste, waste acceptance and analysis, and control of windblown material and litter should not be applicable to medical waste facilities.

Stericycle commented that any restriction on operating hours should be removed.

Significant changes from proposal:

In response to comments received, the executive director recommends the following revisions:

- providing a new provision to allow changes in operating hours and buffer zones as non-notice modifications;
- revising the "putrescible waste" definition to "putrescible medical waste" definition;
- adding electronic submittals and recordkeeping option for future development;
- revising the maximum temporary storage time without a storage registration from 24 to 72 hours for transporters;
- revising the refrigeration requirement for transporters to begin 72 hours after the time of collection whether or not the waste has been refrigerated during pre-collection storage; and
- removing the definitions for "Non-hazardous pharmaceutical waste" and "Trace chemotherapy waste," the requirement that these waste be incinerated, and adding a new sentence to indicate that the executive director may authorize medical waste facilities to store and process other related waste.

Potential controversial concerns and legislative interest:

The commission received two letters dated February 3rd and 18th, 2016 from Representative John Zerwas, M.D. (Author of HB 2244). In these letters, Representative Zerwas asserted that the goals of HB 2244 are to consolidate rules related to medical waste to reduce confusion regarding the applicability of many rules that relate to municipal solid waste landfills and to remove any rules that are not justified by a reasonable basis.

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The executive director has taken these letters into consideration and made corresponding changes.

Does this rulemaking affect any current policies or require development of new policies?

No.

What are the consequences if this rulemaking does not go forward? Are there alternatives to rulemaking?

Failure to adopt amendments to TCEQ rules will result in the commission being out of compliance with THSC, §361.0905.

Key points in the adoption rulemaking schedule:

***Texas Register* proposal publication date:** December 25, 2015

Anticipated *Texas Register* adoption publication date: May 13, 2016

Anticipated effective date: May 19, 2016

Six-month *Texas Register* filing deadline: June 25, 2016

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Attachments

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