



pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION



Bureau of Waste Management

Regulated Medical and Chemotherapeutic Waste Regulations Final Rulemaking

Environmental Quality Board

July 15, 2014

Background

The rulemaking is a comprehensive revision of the commonwealth's existing infectious and chemotherapeutic waste regulations, which will benefit medical practitioners, medical facilities, medical waste transporters and processors of medical waste.

Purpose

- Recognize and promote efficient business practices;
- Provide consistency with federal requirements;
- Provide reasonable management options for medical waste generators; and
- Maintain a high level of protection for public health and the environment.

Affected Parties

All generators, processors and transporters of regulated medical or chemotherapeutic waste currently regulated by the department will be required to comply with the rulemaking.

Summary of Provisions

- Change in terminology from “infectious waste” to “regulated medical waste”
- Changes in manifest requirements
- Changes to the on-site storage requirements
- Provides the authorization to ship medical waste through the U.S. Postal Service Program
- Provides four permits-by-rule for captive waste processing
- Provides three permits-by-rule that authorize standard operating procedures

Economic Impact

- DEP contacted private medical facilities in each sector of the regulated community to calculate the cost savings analysis for this regulation.
 - All facilities contacted expressed that the rulemaking could benefit their operations.
 - None of the facilities surveyed indicated that it would impact their operations negatively.

Economic Impact

The final-form rulemaking is expected to reduce costs by:

- Providing consistency with federal requirements to eliminate dual signage and labeling for interstate waste transportation;
- Increasing on-site waste storage time to eliminate the shipment of partial loads;
- Allowing use of electronic shipping documents to leverage existing business practices and eliminate the need for duplicate paper tracking;
- Providing seven permits-by-rule to reduce the time necessary for DEP to review permit applications and issue permits; and
- Allowing use of the USPS Program for shipping medical waste to provide another shipping option for generators.

Public Participation Process

- The rulemaking was developed in cooperation with the medical industry, vaccine manufacturing industry and those serving the waste management needs of the industry.
- DEP provided briefings on various stages of the rulemaking to the Solid Waste Advisory Committee (SWAC), Citizens Advisory Council (CAC) and Small Business Compliance Advisory Committee (SBCAC)
- DEP received letters of support from SWAC on Sept. 22, 2011 and June 5, 2014.

Public Comments

- Based on public comments, the following revisions were made to the rulemaking:
 - Provided special provisions for wastes generated by the biologics industry.
 - Added flexibility in segregation requirements for chemotherapeutic waste that is incinerated on-site.
 - Allow a vehicle or roll-off to serve as the outermost container for labeling purposes, provided that certain conditions are satisfied.
 - Allow electronic and stamped signatures on shipping documents.

Future Outreach

- DEP staff will provide outreach to the regulated community through:
 - Meetings, fact sheets, other media; and
 - Compliance assistance during routine inspections.

Recommendation

DEP recommends that the board approve the final-form regulation for the management of regulated medical and chemotherapeutic waste.



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Questions?



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