

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Solid and Hazardous Waste Commission

Hazardous Materials and Waste Management Division

6 CCR 1007-2

(Adopted by the Solid and Hazardous Waste Commission on August 16, 2011)

**Statement of Basis and Purpose
and Specific Statutory Authority for**

Addition to Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1) – Deletion and Replacement of Section 13, Medical Waste (previously Infectious Waste) and Associated Additions to Section 1.2, Definitions and Modification of Section 7.1 (D), Transfer Stations

Basis and Purpose

I. Statutory Authority

These modification are made pursuant to the authority granted to the Solid and Hazardous Waste Commission in Sections 25-15-302(4.5) and 30-20-109, C.R.S.

II. House Bill 89-1328

The Colorado Department of Public Health and Environment (the Department) is the state agency responsible for activities related to the federal “Resource Conservation and Recovery Act” (RCRA). RCRA contains requirements for the management of hazardous waste and solid waste. HB89-1328 added a new Part 4 – Infectious Waste to Title 25 Article 15. To implement these statutory requirements, the Department promulgated regulations applicable to all facilities that generate, manage and dispose of infectious waste effective May 30, 1990.

III. Purpose of new regulations:

The purpose of these new regulations is to update the regulations applicable to infectious waste and expand this section to include non-infectious solid wastes including trace chemotherapy waste and waste pharmaceuticals commonly associated with and co-generated in a health care setting. The existing Section 13 has not been modified since 1990 and since that time, some aspects of the existing regulations have become outdated.

In addition, there is increasing awareness of potential environmental impacts associated with disposing of waste pharmaceuticals down the drain. Viable alternatives to disposal down the drain include incineration and disposal in approved landfills designed to contain these wastes. These regulations clarify that landfill disposal of non-hazardous waste pharmaceuticals and other medical wastes can only occur in solid waste sites and facilities that specifically include these wastes in their approved Engineering Design and Operations Plan. Due to the inclusion of additional solid wastes generated in a health care setting, this section will be re-named “Medical Waste.”

Discussion of Regulatory Proposal

- I. The proposed Section 13 regulations require the addition of new definitions. These changes are summarized below. For consistency, these definitional changes are being made to Section 1.2 of the solid waste regulations (6 CCR 1007-2, Part 1).

The following definitions are being added to Section 1.2:

1. Antineoplastic
2. Blood and body fluids
3. Empty container
4. Encapsulation
5. Household medical waste
6. Isolation waste
7. Medical waste
8. Medical waste generator
9. Medical Waste Management Plan
10. Medical waste treatment
11. Pathological waste
12. Pharmaceutical
13. Potentially infectious waste
14. Render non-infectious
15. Reverse distributor
16. Sharps
17. Sharps container
18. Stabilization
19. Trace chemotherapy waste
20. Trauma scene waste

In addition, the following definitions are being modified in Section 1.2:

1. Biohazardous waste
2. Infectious waste

The proposed Section 13 regulations also require the removal of the term “medical waste” from Section 7.1(D) Regulations for Transfer Stations.

II. Scope and applicability (Section 13.1)

This section describes the types of facilities to which these regulations apply. It also describes an exemption to the regulations for household medical waste generators.

III. General Provisions (Section 13.2)

The first general provision in this section declares that no site or facility regulated under this Section 13 can become a health or environmental hazard or allow nuisance conditions to develop. The second general provision clarifies that all sites and facilities that generate, store, consolidate, treat, process, transport or dispose of medical waste must comply with all applicable federal, state and local rules and regulations. The third general provision requires that all records retained as a result of these regulations be maintained onsite in an easily retrievable format. This allows the storage of records in electronic format or hard copy as long as they are accessible at the site or facility for inspection purposes. It also increases the length of time records must be kept to three (3) years to be consistent with other sections of these regulations. The fourth general provision prohibits the compaction of untreated infectious waste prior to treatment.

IV. Certificate of Designation Required (Section 13.3)

This section declares that all medical waste consolidation, storage, treatment, processing and disposal facilities must obtain a Certificate of Designation as a solid waste site or facility. This includes new facilities as well as existing facilities that want to accept untreated medical waste as a new waste stream. It describes four situations where a Certificate of Designation is not required. The first two exemptions are for medical waste generators that temporarily accumulate and/or treat their own medical waste onsite if they meet certain minimum requirements. The next exemption is for entities that conduct medical waste consolidation and short-term storage activities as a community service limited to only households. The final exemption is for facilities that have been issued a Certificate of Designation under the hazardous waste provisions in Title 25 Article 15 Parts 1, 2, 3 and 5.

V. Standards for Medical Waste Generators (Section 13.4)

This section contains language equivalent to 25-15-403 regarding the generator medical waste management plan and was included since many generators appear to be unaware of the statutory requirements. Inclusion of these provisions in the regulations makes it easier for generators to understand the need for the plan and the elements that must be included in their plan.

VI. Standards for Commercial Medical Waste Storage Facilities (Section 13.5)

This section describes the requirements for commercial medical waste storage facilities used for the consolidation and short-term storage of untreated medical wastes prior to

shipment to an approved treatment or disposal facility. The need for such facilities was identified during the stakeholder process as a new type of solid waste facility that would allow for more efficient collection and handling of medical wastes from multiple generators in a manner that would be protective of human health and the environment. Due to the nature of the wastes handled, the Department felt it was more appropriate for these wastes to be managed in facilities that have obtained a Certificate of Designation and have an approved Engineering Design and Operations Plan to ensure proper management of larger quantities of medical wastes rather than at solid waste transfer stations with less oversight. Medical waste storage facilities would also be subject to training requirements, applicable fees, financial assurance, inspections and enforcement requirements.

VII. Standards for Medical Waste Treatment (Section 13.6)

This section clarifies that treatment of infectious medical wastes is any method that renders the waste non-infectious. Non-infectious means the waste has been treated to achieve widely accepted pathogen inactivation standards. It also clarifies which treatment methods are considered acceptable for trace chemotherapy and pharmaceutical waste. This section specifies that treatment technology manufacturers must develop appropriate validation test methods to verify for the Department that their overall technology and specific equipment perform as designed and are able to consistently treat medical waste to acceptable standards. Furthermore, technology manufacturers must determine appropriate verification test methods that can be done on a routine basis by the waste treater to verify for the Department that the treatment process is operating effectively onsite under actual operating conditions. This information must be made available to the medical waste treater for inclusion in their medical waste management plan or application for Certificate of Designation as applicable.

VIII. Engineering Design and Operation Plan Requirements for Commercial Storage and Treatment Facilities (Section 13.7)

This section specifies the requirements for Engineering Design and Operations Plans for owners and operators of commercial storage and treatment facilities. The Engineering Design and Operations Plan must be provided to the Department and local governing body as part of the application for a Certificate of Designation for review and approval prior to acceptance of any medical waste. This section provides the minimum requirements for the Engineering Design and Operations Plan, including a list of prohibited wastes, maps, general site operating plan, description of job duties, technology validation and verification procedures for treatment facilities, waste characterization, screening and acceptance plans, on- and off-site controls to prevent nuisance conditions, waste handling and storage, waste tracking, fire prevention/contingency plans, personnel training plan, and closure plan. Facilities regulated under this section would be subject to applicable fees, financial assurance, inspections and enforcement.

IX. Operating Requirements for Commercial Storage and Treatment Facilities (Section 13.8)

This section specifies the minimum operating requirements for commercial storage and treatment facilities. It includes required facility operational notifications, operational requirements, required facility self-inspections, access controls, and recordkeeping and closure requirements.

X. Standards for Medical Waste Disposal (Section 13.9)

The first provision in this section describes the final disposition requirements for recognizable human anatomical remains. The second provision clarifies that untreated infectious waste can only be disposed of in a solid waste site or facility that has an approved Engineering Design and Operations Plan that specifically includes this waste. It also clarifies that properly treated infectious waste may be disposed of with normal solid waste. The final provision identifies disposal alternatives for trace chemotherapy waste and waste pharmaceuticals, and clarifies that if these options aren't available, such wastes can only be disposed of in a solid waste site or facility that has an approved Engineering Design and Operations Plan that specifically includes these wastes.

XI. Transportation Requirements (Section 13.10)

This section clarifies that medical waste can only be transported to an approved solid waste site or facility unless exempted under Section 13.3.1 for generators that self-transport their own waste. It also describes the actions that the transporter must take in the event of a spill or release of medical waste during transportation.

Issues Encountered During Stakeholder Process:

Outdated: The statute references the 1986 “EPA Guide for Infectious Waste Management.” Since then, the State and Territorial Association on Alternative Treatment Technologies (STAATT) has defined widely accepted pathogen inactivation standards for infectious waste treatment and developed processes states can use when evaluating new treatment technologies. There have also been important advancements in the concepts of Universal/Standard Precautions by the Centers for Disease Control (CDC), Bloodborne Pathogens by the Occupational Safety and Health Administration (OSHA) and transportation requirements by the US Department of Transportation (US DOT) and United States Postal Service (USPS), including extensive training and specific management requirements.

Limited Scope: In the current solid waste regulations, Section 13 applies only to infectious waste. Since this section was promulgated, however, there has been increasing awareness of potential human health and environmental impacts associated with undesirable disposal practices for pharmaceutical wastes generated in a health care setting. The Department felt this would be a good opportunity to modify the regulations by broadening the scope of Section 13 to include trace chemotherapy waste and waste

pharmaceuticals that can impact human health and the environment if not properly disposed. Since these wastes are already solid waste, inclusion in Section 13 does not increase the regulatory burden on facilities and only serves to clarify and reinforce ongoing efforts by the Hazardous Waste Compliance Assurance Unit to increase awareness of issues related to health care waste management and disposal.

Conflicting Terminology: Infectious waste is regulated by several federal and state agencies, each with its own terminology but often overlapping requirements. Every effort was made to be consistent with other regulatory programs where possible, and define terms as used in these regulations where necessary. Although this means that several terms will be added to Section 1.2 Definitions, the stakeholders felt it was important to clarify the meaning of terminology used in Section 13 and distinguish it from similar sounding terms used in other regulatory programs.

Regulatory Alternatives

1) The Department receives numerous calls each year from medical waste generators regarding onsite medical waste management requirements. Many are unaware of the requirements for the generator medical waste management plan, which is available only in the infectious waste statute (25-15-403), or want more specific details and best management practices to incorporate into their plan. An alternative to expand and clarify the requirements for medical waste generators was considered because the statute has only general requirements for a generator medical waste management plan and relies heavily on voluntary compliance with recommendations in the 1986 “EPA Guide for Infectious Waste Management.” This alternative was rejected because the statute (25-15-401) specifically declares that no rules or regulations governing generators are necessary for implementation of the statute. Since the regulations are more readily available, and generators appear to be more aware of them than the statute, the decision was made to insert equivalent language to 25-15-403 regarding the generator medical waste management plan into the regulations as Section 13.4.

2) The solid waste statute (30-20-102) says anyone that operates a solid waste disposal site or facility has to obtain a Certificate of Designation. By definition, solid waste disposal includes “storage, treatment, utilization, processing and final disposal.” There is no exemption for generators regarding the Certificate of Designation, except a limited one under the “one’s own waste” provision. This exemption cannot be used by governmental entities, however, which includes a significant number of community and public health facilities. An alternative to require all medical waste generators to obtain a Certificate of Designation was rejected because the Department does not believe it was the intent of the Legislature to issue a Certificate of Designation to every generator that wants to store and/or treat their own medical waste onsite. The decision was made instead to use Department discretion to adopt limits below which a facility is deemed to be an approved facility for which it is not necessary to obtain a Certificate of Designation. The limits selected were by consensus of the stakeholder group, with packaging and time being key elements to prevent nuisance conditions for putrescible wastes. The limits were

based on best management practices that many of the stakeholders indicated they were already following. These limits should not increase the regulatory burden for generators that ship waste offsite because these wastes have to be packaged for shipment anyway. The limits should not be a significant burden for generators that treat their waste onsite because they normally treat their waste without placing it in storage first. In case they can't, the generator would include proper packaging for temporary storage in their contingency plan as part of their generator medical waste management plan to manage their medical waste in the event of equipment failure, transportation delays or other unplanned events.

3) Until recently, non-hazardous waste pharmaceuticals were routinely disposed of down the drain or sent to a municipal solid waste landfill dispersed in the regular trash stream. When pharmaceuticals started being detected in surface water resources, people became aware that these substances were not being treated by wastewater treatment plants and were being discharged to surface waters in sufficient quantities to cause environmental impacts. To reduce impacts to surface water, disposal down the drain is now discouraged and incineration or landfill disposal are encouraged. In the last few years, pharmaceutical take-back programs have developed that gather enormous quantities of waste pharmaceuticals for disposal. Some of these are sent for incineration in out-of-state solid waste or hazardous waste incinerators, but this is very expensive. Some of these are sent for disposal in certain legacy local municipal solid waste landfills that may not fully meet RCRA Subtitle D design requirements that better contain concentrated quantities of mixed waste pharmaceuticals.

An alternative was considered to require landfills that want to accept this new untreated waste stream to conduct tests to prove their liner system is adequate to contain concentrated quantities of a wide variety of mixed pharmaceutical wastes and prevent releases to groundwater. Although this is still an available option, requiring this alternative was rejected as being too burdensome and costly for the landfills. The decision was made instead to use the concept of protecting groundwater by encouraging methods that cause waste pharmaceuticals to undergo a fundamental physical or chemical change that either destroys the waste (e.g., incineration) or renders it less leachable in the landfill (e.g., encapsulation or stabilization). Both methods reduce the waste's potential to impact groundwater by destroying or immobilizing the constituents of concern similar to what is done in the hazardous waste regulations under the land disposal restrictions (LDR). Details on how waste pharmaceuticals are destroyed or rendered less leachable would be included in the Engineering Design and Operations Plan submitted as part of the application for a new or modified Certificate of Designation. Treatment can be conducted either by a medical waste treatment facility or by a solid waste disposal facility approved to treat waste pharmaceuticals prior to disposal. Solid waste disposal sites and facilities will be required to specifically state in their Engineering Design and Operations Plan if they are able to accept treated or untreated infectious waste, trace chemotherapy waste and/or waste pharmaceuticals.

Incorporated by Reference Regulatory Citations

The materials and regulations listed below are available for examination at the state depository libraries or may be obtained by contacting:

Regulatory and Program Authorization Coordinator
Colorado Department of Public Health and Environment
Hazardous Materials and Waste Management Division
4300 Cherry Creek Drive South
Denver, CO 80246-1530

- 49 CFR 173.196 US DOT - Category A infectious substances (packaging).
- 49 CFR 173.197 US DOT - Regulated medical waste (packaging).
- 21 CFR 1307.11 DEA - Distribution by dispenser to another practitioner or reverse distributor.
- 21 CFR 1307.21 DEA - Procedure for disposing of controlled substances.
- 21 USC Sec. 802(6) - Controlled Substances Act Definitions
- 6 CCR 1011-1 Chapter II Part 7.200 et seq. – Donation of unused medications, medical devices and medical supplies.
- 6 CCR 1015-10 – Cancer drug repository program