



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

MAR 3 2003

Caryn M. Bing, Rph, MS, FASHP
President
CB Healthcare Consulting
12 Pine Tree Lane
Burr Ridge, IL 60527

Reference No. 02-0098

Dear Ms. Bing:

This is in response to your letter and telephone conversation with Eileen Edmonson of my staff concerning the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a commercial home health care provider who removes "Regulated medical waste (RMW), 6.2, UN 3291, PG II" from a private home for return to the provider's facility for subsequent disposal. We apologize for the delay in responding and any inconvenience this may have caused. Your questions are paraphrased and answered below.

Q1. Are there any provisions that except commercial home health care providers from any or all of the requirements in the HMR for transporting regulated medical waste?

A1. We revised the HMR requirements for transporting RMW in a recent final rule (Docket No. RSPA-98-3971 (HM-226), copy enclosed). Under revised § 173.6, RMW and other Division 6.2 (infectious substance) materials, other than Risk Group 4, may be excepted from certain requirements as materials of trade (MOTs) when transported by a private carrier in direct support of a principal business that may not be transportation of goods by motor vehicle. The MOTs exception provides for RMW that is generated through home treatment of medical conditions and is transported elsewhere for disposal by the medical provider.

In addition, revised § 173.134(c)(1) and (c)(2) permit RMW that does not contain a culture or stock to be transported by a private or contract carrier in a non-bulk, non-specification packaging that satisfies the requirements in §§ 173.24 and 173.24a of the HMR and the Occupational Safety and Health Administration's (OSHA's) regulations in 29 CFR 1910.1030. Each container must be marked with the OSHA "BIOHAZARD" marking and with the proper shipping name, identification number, and additional information required in 49 CFR Part 172, Subpart D.

Q2a. Is a sealed sharps container an authorized hazardous materials package under the HMR or must it be placed in another type of packaging to be acceptable in transportation?



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173.134

- A2a. Revised § 173.6(a)(4) prescribes the use of a combination packaging. Specifically, this section permits a sharps container constructed of a rigid material resistant to punctures and leaks to be used as an inner packaging. The sharps container must be placed in an outer packaging that is strong, tight, securely closed and secured against movement during transportation. Revised § 173.197(b) permits sharps and sharps with residual fluid in a single or combination, non-bulk, puncture-resistant packaging that meets the requirements in 49 CFR Part 178, Subpart M, at the Packing Group II performance level.
- Q2b. What type of outer packaging must the home health care provider use to transport receptacles (e.g., sharps containers) containing RMW? Are there requirements for this packaging under the HMR?
- A2b. RMW sharps may be transported in packagings that meet the requirements in revised § 173.6, 173.134, 173.196 or § 173.197, as applicable. Sections 173.6(a)(4)(ii) and 173.196(a) require RMW to be placed in a combination packaging. Sections 173.134(c)(1) and (c)(2), and 173.197(b) require RMW to be placed in a single or combination packaging depending on the packaging's design type and performance and whether or not a combination packaging is required under 29 CFR 1910.1030.
- Q2c. Are there non-bulk packagings available for purchase today marked to show they are "DOT approved" for transporting RMW?
- A2c. A packaging that meets the requirements in revised § 173.197(b) is a non-bulk packaging that conforms to a UN standard at the Packing Group II performance level and is required to be marked with a UN standard marking as prescribed in 49 CFR Part 178, Subpart L. See for example § 178.503. A infectious substance packaging that meets revised § 173.196 is a non-bulk packaging that is required to be marked as prescribed in § 178.503(f). A packaging that meets the exceptions in revised § 173.6 or § 173.134 is a non-bulk, non-specification packaging.
- Q2d. Must a "mail-back" packaging that meets U.S. Postal Service requirements for transporting RMW also meet RMW packaging requirements under the HMR? That is, a mail-back package containing RMW sealed in the patient's home would be transported by the home health provider to his or her organization's designated place of business.
- A2d. Yes, a mail-back package containing RMW transported by a commercial home health care provider is subject to the HMR and must meet applicable requirements.
- Q3. What type of documentation (e.g., a manifest or shipping paper) is required for home health care providers transporting RMW?
- A3. Unless excepted from the shipping paper requirements under the MOT exceptions or the terms of a DOT exemption or approval, RMW in commercial transportation must be

accompanied by a shipping paper prepared in accordance with 49 CFR Part 172, Subpart C. The HMR do not specify a particular format for shipping papers. Under § 171.8, a shipping paper may be a shipping order, bill of lading, manifest or other shipping document serving a similar purpose.

- Q4a. What training must a home health care provider receive to transport RMW from a patient's home?
- A4a. The home health care provider must receive hazmat training as prescribed in 49 CFR Part 172, Subpart H. Since the employee packages and transports RMW, the employee must receive function-specific training to ensure the employee is knowledgeable in those areas and can determine that a shipment is in compliance with the requirements of the HMR. The employee must also receive general awareness and safety training. See § 172.704(a)(1) and (a)(3).
- Q4b. Does the DOT have any training resources available that outline the function-specific training required for this limited scope of transporting RMW?
- A4b. We offer courses and workshops on transporting infectious substances, including RMW, that may assist with function-specific training (pamphlets enclosed). However, the hazmat employee's job tasks may include equipment and materials that might not be discussed. The hazmat employer is responsible for ensuring each hazmat employee's training is sufficient to provide the employee with the knowledge, skills, and abilities to perform their individual job function. This training may be provided by the hazmat employer or other public or private sources, such as outside training firms or consultants, Federal or State agencies, colleges and universities, or any other organization offering training that meets the objectives.
- Q4c. What are the timing requirements for training an employee transporting RMW under these type of conditions?
- A4c. Section 172.704(c)(1) requires that a new hazmat employee or a hazmat employee who changes job functions must complete their hazmat training within 90 days after employment or job function change. However, they may perform the job functions prior to the completion of training under the direct supervision of a trained and knowledgeable hazmat employee. When RSPA adopts a new regulation or changes an existing regulation that relates to a function performed by a hazmat employee, the hazmat employee must be instructed in the new or revised function-specific requirements as soon as possible without regard to the three-year training cycle. It is not necessary to completely retrain the employee in this instance. Only instruction that is necessary to assure knowledge of the new or revised regulatory requirement is required.
- Q4d. How often must hazmat training be repeated?

- A4d. A hazmat employee must receive the required training at least once every three years.
- Q4e. What type of record keeping is required for hazmat training? How long must these records be kept?
- A4e. Section 172.704(d) requires that a record of current training, inclusive of the past three years, be kept by each hazmat employer for each hazmat employee while that employee is employed as a hazmat employee and for 90 days thereafter. This means each hazmat employer is required to retain the most current training records and the training records from the previous three-year training cycle. It is not necessary to retain records of remedial instruction, discussed in our response under A4c, that is provided for new or revised requirements until the next scheduled retraining at or within the three-year cycle.
- Q5. Are there additional regulations on the transportation of RMW under the HMR that have not been identified in this inquiry?
- A5. The answer is yes, but they are too numerous to discuss in this response. The HMR include requirements on hazardous materials identification, classification, description, packing, marking, labeling, placarding, and shipping papers, as well as mode-specific carrier instructions for loading, unloading and handling hazardous materials in transit. Exceptions apply to some of the transportation scenarios discussed in your inquiry, but not to all.

I hope this satisfies your request.

Sincerely,



Hattie L. Mitchell, Chief
Regulatory Review & Reinvention
Office of Hazardous Materials Standards

Enclosures

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Edmonson
§173.134
Regulated Medical
Waste
02-0098

June 6, 2002

Edward T. Mazzullo
Director, Office of Hazardous Material Standards
US Department of Transportation/RSPA (DHM-10)
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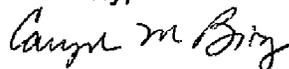
RE: Clarification of Document No 00-0295

Dear Mr. Mazzullo:

In the above referenced letter to Ms. Alice Jacobsohn, Esq. dated September 26, 2001, you clarified that the 'household' exemption to 49 CFR § 173.134(b) does not apply if a home health care provider removes regulated medical waste (RMW) from a private home for disposal elsewhere. I would like to be sure that I understand the implications of the applicability Hazardous Materials Regulations (HMR) to commercial home care providers, many of whom have historically needed only a limited background in DOT and HMR regulations. My interest relates to the transportation of materials that can be classified as RMW which are removed from the premises by a commercial home care provider, not to waste that may be generated by an individual in a private residence and treated as household waste exempted from HMR.

I have included specific questions in the attached outline. If there are additional issues that you would like to clarify related to DOT and HMR applicability to commercial home care providers, that would also be appreciated. Thank you for your assistance in this matter.

Sincerely,



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attachment

Attachment to June 6, 2002 letter to Mr. Edward Mazzullo, Director, Office of Hazardous Materials Substances, US Department of Transportation

Questions regarding applicability of Hazardous Materials Regulations (HMR) regarding Regulated Medical Waste (RMW) to home health care providers:

1. Quantity of RMW:

Is there an quantity (volume or weight) of RMW below which HMR might exempt a commercial home care provider from any or all of the regulations regarding transporting RMW (such as when a home care nurse carries a small sharps container from a patient's home back to the agency for appropriate holding and subsequent disposal according to HMR?)

2. Packaging Requirements for Transporting RMW:

Is a sealed sharps container sufficient to meet HMR, or does the provider need to use a special type of packaging to hold these receptacles during transport?

If required, what type of outer packaging must a home care provider use to transport receptacles (i.e. sharps containers) containing RMW (are there specifications for these in the HMR?)

Are there specific types of packaging available on the market today that are noted as 'DOT approved' for these purposes?

If a home care provider uses a 'mail back' system that meets US Postal Services requirements for shipping RMW, would the proper use of this packaging meet HMR (i.e. sealed in the home prior to transporting to the home care provider organization's designated place of business?)

3. Documentation:

What type of documentation (e.g. manifest/shipping paper) is required for the transportation of RMW generated and transported under these conditions?

Attachment to June 6, 2002 letter to Mr. Edward Mazzullo, Director, Office of Hazardous Materials Substances, US Department of Transportation

4. Training Requirements for Commercial Home Health Care Providers:

What specific HazMat training is required for home care provider personnel who transport RMW from patient homes?

Does the DOT have any specific resources available that outline the function-specific training required for this limited scope transporting of RMW?

What are the HMR requirements regarding the timing of any special training for transporting RMW under these types of conditions?

How often must special training that meets HMR be repeated?

What type of record keeping is required for training, and how long must these records be retained.

5. Additional requirements or issues:

Are there any additional issues in the HMR related to this type of RMW that have not been identified in this inquiry?