U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

APR 0 2 2012

Mr. Eric Smith
Vice President of Operations
Waste and Compliance Management, Inc.
6054 Corte del Cedro
Carlsbad, CA 92011

Reference No. 12-0028

Dear Mr. Smith:

This is in response to your January 17, 2012 letter concerning how to describe and transport disposal and recycling products, including sharps, used by medical facilities to treat human and animal patients under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You state your company obtains these materials from clinics, dental offices, veterinary practices, occupational medicine providers, long-term care facilities, and other commercial and government entities. We have paraphrased your questions and answered them as follows.

Q1. Is it permissible to ship sharps that have been used to administer medicine and/or other wastes by a commercial motor carrier, such as United Parcel Service (UPS), if they are classified as "Used healthcare products" under the HMR?

A1. The answer is no. Products, including sharps, used by medical facilities to treat humans and animals that are suspected of being contaminated with a Category B, Division 6.2 (infectious substance) material and intended to be transported for disposal or recycling meet the definition provided in § 173.134(a)(5) for a "UN 3291, Regulated medical waste, n.o.s., 6.2, PG II." If these products are suspected of being contaminated with a Category A, Division 6.2 material, that product must be classed and described as either "UN 2814, Infectious substances, affecting humans, 6.2" or "UN 2900, Infectious substances, affecting animals, 6.2," as applicable. The HMR defines a used health care product as a medical, diagnostic, or research device or piece of equipment, or a personal care product that is used by consumers, medical professionals, or pharmaceutical providers, and is removed from its original packaging, contaminated with potentially infectious body fluids or materials, and not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation. Further, it does not meet the definition of a patient specimen, biological product, or regulated medical waste (see § 173.134(a)(8)). The HMR excepts used health products from regulation if they are being returned to the

manufacturer or the manufacturer's designee and: 1) conform to the Department of Labor, Occupational Safety and Health Administration's (OSHA's) regulations for bloodborne pathogens under 29 CFR 1910.1030, or 2) are packaged and transported as prescribed in § 173.134(b)(12)(ii). If used health care products intended for transportation do not conform to the OSHA standard or the exception in § 173.134(b)(12)(ii), they must comply with regulations prescribed in § 173.199.

Q2. If the answer to question Q1 is yes, please specify which HMR section(s) must we follow?

A2. The answer is no. See answer A1.

Q3. If the answer to question Q1 is no, what are the consequences under the HMR for improperly classifying and shipping hazardous materials?

A3. Each person who offers a hazardous material for transportation or transports a hazardous material in commerce is responsible for compliance with the requirements of the HMR, or a special permit, approval, or registration issued under the HMR, with respect to any regulated function that the person performs or is required to perform. Under 49 CFR Part 107, Subpart D, the civil penalty for knowingly violating the Federal hazardous materials transportation law (49 U.S.C. 5101, et. seq.) or the HMR can range from $275 to $55,000 per violation per day, or up to $110,000 if the violation results in death, serious illness, severe injury to any person, or substantial destruction of property. A minimum fine of $495 applies to violations relating to training. See §§ 107.329 and 107.333. Criminal penalties may include fines and imprisonment from 5 to 10 years based on the severity of the crime. Penalties for violations of the HMR are assessed on a case-by-case basis and depend on a number of factors, including the nature, circumstances, extent, and gravity of the violation.

Q4. Which office or department within your organization is the final authority on how to classify hazardous materials and any challenges to a product's classification that can be made?

A4. Under § 173.22, it is the shipper's responsibility to properly classify a hazardous material before it is offered for or transported in commerce. The Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), is the competent authority responsible for the control and regulation of the transportation of hazardous materials in the United States (see § 171.8, "Competent authority" definition). However, disputes concerning the classification of a hazardous material are typically deferred to the appropriate staff in PHMSA's Sciences Branch, Engineering and Research Division, telephone number (202) 366-4545.

Finally, in your letter, you also mention these materials are sometimes shipped by governmental agencies. The HMR applies to the transportation of hazardous materials in commerce. The HMR does not apply to the transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a Federal, state, or local government employee solely for noncommercial governmental purposes because such transportation is not considered to be "in commerce" (see § 171.1(d)(5)). Thus, if a government agency's employees prepare and transport a hazardous material for transportation, that material is not subject to the HMR. However, if a government agency contracts with a third party to class, package, prepare shipping documentation, load, or transport hazardous waste on its behalf, the contractor must comply with all applicable HMR requirements.

I hope this satisfies your request.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

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January 17, 2012

JAN 23 2012

Mr. John Gale, Director
PHMSA
1200 New Jersey Avenue SE
Washington, DC 20590

PROPER CLASSIFICATION OF USED, POTENTIALLY INFECTIOUS SHARPS

Mr. Gale,

We manufacture disposal and recycling products used by medical clinics, dental offices, veterinary practices, occupational medicine providers, long-term care facilities and other commercial and government entities. Several of our products are used by generators to dispose of 'sharps,' including needles and syringes, which have been used in the treatment of human or animal patients and may be infectious.

Our Isolyser®/SMS®m products are approved by the United States Postal Service (Domestic Mail Manual, Reference 601.10.17.5 for shipment of UN3291 Sharps and N3291 Regulated Medical Waste) for mailing these materials from generator locations to our facility.

For several reasons, we would like the option to ship these packages using the United Parcel Service (UPS) network from the generator to our facility. However, because UPS has not adopted the Domestic Mail Manual, they do not allow the shipment of Regulated Medical Waste through their network, regardless of United States Postal Service approval status.

It has come to our attention that one of our competitors has classified a product with the exact same characteristics, use and purpose as our sharps mail-back product as 'Used Healthcare Products.' By using the classification of "Used Healthcare Products," their customers are shipping used sharps and other potentially infectious waste via UPS.

Because UPS regulations prohibit shipping Regulated Medical Waste, we believe the competitor simply classified their packages as "Used Healthcare Products," for the purpose of shipping packages via UPS without scrutiny.

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Their product is marketed to generators of used needles, syringes, and other healthcare materials from human and animal patients.

With that background information in mind, please provide direction concerning the following questions:

Is it legal to ship sharps, which have been used to administer medicine and/or other waste via motor carrier such as UPS, simply by classifying that material as "Used Healthcare Products?"

If yes, please specify which rule section(s) we must follow?

If the answer is no, what is the consequence for improperly classifying and shipping items?

Further, which organization or department within your organization is the final authority regarding classification and challenges that may be made?

Thank you.

Eric Smith
VP of Operations
WCM, Inc.

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