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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2011-0294 (PDA-35(R))]

NEW JERSEY REGULATIONS ON
TRANSPORTATION OF REGULATED MEDICAL WASTE

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Public notice and invitation to comment.

SUMMARY: Interested parties are invited to comment on an application by the Healthcare Waste Institute (Institute) for an administrative determination as to whether Federal hazardous material transportation law preempts regulations of the New Jersey Department of Environmental Protection (NJDEP) which apply to the transportation of regulated medical waste in commerce, including the packaging of regulated medical waste for transportation; marking and labeling of containers of regulated medical waste offered for transportation or transported; the description of regulated medical waste on documents accompanying shipments of regulated medical waste and the use and retention of such documents; and the marking of vehicles which transport regulated medical waste.

DATES: Comments received on or before [insert date 45 days after date of publication in the Federal Register] and rebuttal comments received on or before [insert date 90 days after date of publication in the Federal Register] will be considered before an

administrative determination is issued by PHMSA's Chief Counsel. Rebuttal comments may discuss only those issues raised by comments received during the initial comment period and may not discuss new issues.

ADDRESSES: The Institute's application and all comments received may be reviewed in the Docket Operations Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC 20590. The application and all comments are available on the U.S. Government Regulations.gov website: <http://www.regulations.gov>.

Comments must refer to Docket No. PHMSA-2011-0294 and may be submitted by any of the following methods:

- *Federal eRulemaking Portal*: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Fax*: 1-202-493-2251.
- *Mail*: Docket Operations Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC 20590.
- *Hand Delivery*: Docket Operations Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

A copy of each comment must also be sent to (1) Alice P. Jacobson, Esq., Director, Healthcare Waste Institute, 4301 Connecticut Avenue, NW, Suite 300,

Washington, DC 20008, and (2) Mary Jo M. Aiello, Administrator, New Jersey Department of Environmental Protection, Solid and Hazardous Waste Management Program, Mail Code 401-02C, P.O. Box 420, Trenton, NJ 08625-0420. A certification that a copy has been sent to these persons must also be included with the comment. (The following format is suggested: “I certify that copies of this comment have been sent to Mses. Jacobson and Aiello at the addresses specified in the Federal Register.”)

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing a comment submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477-78), or you may visit <http://www.regulations.gov>.

A subject matter index of hazardous materials preemption cases, including a listing of all inconsistency rulings and preemption determinations, is available through PHMSA’s home page at <http://phmsa.dot.gov>. From the home page, click on “Hazmat Safety Community,” then on “Regulations,” then on “Preemption Documents” under “Chief Counsel’s Decisions.” A paper copy of the index will be provided at no cost upon request to Mr. Hilder, at the address and telephone number set forth in FOR FURTHER INFORMATION CONTACT below.

FOR FURTHER INFORMATION CONTACT: Frazer C. Hilder, Office of Chief Counsel (PHC-2), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue, SE, Washington, DC 20590; telephone No. 202-366-4400; facsimile No. 202-366-7041.

SUPPLEMENTARY INFORMATION:

I. Application for a Preemption Determination

The Institute has applied to PHMSA for a determination whether Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.*, preempts requirements in Subchapter 3A of Title 7, Chapter 26 of the New Jersey Administrative Code, on the transportation of regulated medical waste in commerce regarding:

- Packaging regulated medical waste for transport off-site, in Sections 7:26-3A.10 (segregation of sharps, fluids (greater than 20 cc), and “other” regulated medical waste); 7:26-3A.11 (“oversized” regulated medical waste that is “too large to be placed in a plastic bag or standard container”); and 7:26-3A.27(g) (conditions when a transporter must comply with “pre-transport” requirements).
- Labeling and marking containers of regulated medical waste with additional information, in Sections 7:26-3A.14 and 7:26-3A.15, respectively, and 7:26-3A.28(c) (additional labeling by a “subsequent transporter” when “regulated medical waste is handled by more than one transporter”).
- Preparation, use, and retention of a “tracking form” describing a shipment of regulated medical waste, in Sections 7:26-3A.19, 7:26-3A.21, 7:26-3A.28, 7:26-3A.31 through 7:26-3A.34, 7:26-3A.41, and (with respect to rail transporters) 7:26-3A.45 & 7:26-3A.46.¹
- Preparation and retention of “exception reports,” in Sections 7:26-3A.21, 7:26-3A.22, and 7:26-3A.36.

¹ In its application, the Institute refers to Section 7:26-3A.47 (“Alternative or innovative technology authorization”), but it seems clear that it meant to refer to Section 7:26-3A.46 (“Rail shipment tracking form requirements”).

- Marking a motor vehicle used to transport regulated medical waste with additional information, in Section 7:26-3A.30.

In summary, the Institute contends that these requirements are preempted because they are (1) not “substantively the same as” requirements in the Federal hazardous material transportation law or the Hazardous Materials Regulations (HMR), 49 CFR parts 171-180, on the transportation of regulated medical waste, or (2) otherwise an “obstacle” to accomplishing and carrying out Federal hazardous material transportation law and the HMR, as the NJDEP requirements are enforced and applied. The Institute notes that certain non-Federal requirements on the transportation of medical waste have been found to be preempted in Preemption Determination (PD) No. 23(RF), “Morrisville, PA Requirements for Transportation of ‘Dangerous Waste,’” 66 FR 37260 (July 17, 2001), decision on petition for reconsideration, 67 FR 2948 (Jan. 22, 2002), and PD-29(R), “Massachusetts Requirements on the Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste,” 69 FR 34715 (June 22, 2004). As explained in those decisions, DOT regulates the transportation of regulated medical waste as a Division 6.2 hazardous material. PD-23(RF), 66 FR at 37260-61; PD-29(R), 69 FR at 34717.² *See also* 49 CFR 173.134(a)(5).

II. Federal Preemption

Section 5125 of 49 U.S.C. contains express preemption provisions relevant to this proceeding. As amended by Section 1711(b) of the Homeland Security Act of 2002 (Pub. L. 107-296, 116 Stat. 2320), 49 U.S.C. 5125(a) provides that a requirement of a

² In 1991, after a two-year demonstration program, the U.S. Environmental Protection Agency (EPA) decided not to regulate medical waste, so that medical waste is not a “hazardous waste” under the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.* *Id.*

State, political subdivision of a State, or Indian tribe is preempted -- unless the non-Federal requirement is authorized by another Federal law or DOT grants a waiver of preemption under § 5125(e) -- if

(1) complying with a requirement of the State, political subdivision, or tribe and a requirement of this chapter, a regulation prescribed under this chapter, or a hazardous materials transportation security regulation or directive issued by the Secretary of Homeland Security is not possible; or

(2) the requirement of the State, political subdivision, or tribe, as applied or enforced, is an obstacle to accomplishing and carrying out this chapter, a regulation prescribed under this chapter, or a hazardous materials transportation security regulation or directive issued by the Secretary of Homeland Security.

These two paragraphs set forth the "dual compliance" and "obstacle" criteria that PHMSA's predecessor agency, the Research and Special Programs Administration, had applied in issuing inconsistency rulings prior to 1990, under the original preemption provision in the Hazardous Materials Transportation Act (HMTA). Pub. L. 93-633 § 112(a), 88 Stat. 2161 (1975). The dual compliance and obstacle criteria are based on U.S. Supreme Court decisions on preemption. *Hines v. Davidowitz*, 312 U.S. 52 (1941); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Ray v. Atlantic Richfield, Inc.*, 435 U.S. 151 (1978).

Subsection (b)(1) of 49 U.S.C. 5125 provides that a non-Federal requirement concerning any of the following subjects is preempted -- unless authorized by another Federal law or DOT grants a waiver of preemption -- when the non-Federal requirement is not "substantively the same as" a provision of Federal hazardous material transportation law, a regulation prescribed under that law, or a hazardous materials security regulation or directive issued by the Department of Homeland Security:

(A) the designation, description, and classification of hazardous material.

(B) the packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(C) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(D) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(E) the designing, manufacturing, fabricating, inspecting, marking, maintaining, reconditioning, repairing, or testing a package, container, or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous material.³

To be "substantively the same," the non-Federal requirement must conform "in every significant respect to the Federal requirement. Editorial and other similar *de minimis* changes are permitted." 49 CFR 107.202(d).⁴

The 2002 amendments and 2005 reenactment of the preemption provisions in 49 U.S.C. 5125 reaffirmed Congress's long-standing view that a single body of uniform Federal regulations promotes safety (including security) in the transportation of hazardous materials. More than thirty years ago, when it was considering the HMTA, the Senate Commerce Committee "endorse[d] the principle of preemption in order to preclude a multiplicity of State and local regulations and the potential for varying as well

³ Subparagraph (E) was editorially revised in Sec. 7122(a) of the Hazardous Materials Transportation Safety and Security Reauthorization Act of 2005, which is Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU), Pub. L. 109-59, 119 Stat. 1891 (Aug. 10, 2005). Technical corrections to cross-references in subsections (d), (e), and (g) were made in Pub. L. 110-244, Sec. 302(b), 122 Stat. 1618 (June 6, 2008).

⁴ Additional standards apply to preemption of non-Federal requirements on highway routes over which hazardous materials may or may not be transported and fees related to transporting hazardous material. *See* 49 U.S.C. 5125(c) and (f). *See also* 49 CFR 171.1(f) which explains that a "facility at which functions regulated under the HMR are performed may be subject to applicable laws and regulations of state and local governments and Indian tribes."

as conflicting regulations in the area of hazardous materials transportation." S. Rep. No. 1102, 93rd Cong. 2nd Sess. 37 (1974). When Congress expanded the preemption provisions in 1990, it specifically found:

(3) many States and localities have enacted laws and regulations which vary from Federal laws and regulations pertaining to the transportation of hazardous materials, thereby creating the potential for unreasonable hazards in other jurisdictions and confounding shippers and carriers which attempt to comply with multiple and conflicting registration, permitting, routing, notification, and other regulatory requirements,

(4) because of the potential risks to life, property, and the environment posed by unintentional releases of hazardous materials, consistency in laws and regulations governing the transportation of hazardous materials is necessary and desirable,

(5) in order to achieve greater uniformity and to promote the public health, welfare, and safety at all levels, Federal standards for regulating the transportation of hazardous materials in intrastate, interstate, and foreign commerce are necessary and desirable.

Pub. L. 101-615 § 2, 104 Stat. 3244. (In 1994, Congress revised, codified and enacted the HMTA "without substantive change," at 49 U.S.C. Chapter 51. Pub. L. 103-272, 108 Stat. 745 (July 5, 1994).) A United States Court of Appeals has found uniformity was the "linchpin" in the design of the Federal laws governing the transportation of hazardous materials. *Colorado Pub. Util. Comm'n v. Harmon*, 951 F.2d 1571, 1575 (10th Cir. 1991).

III. Preemption Determinations

Under 49 U.S.C. 5125(d)(1), any person (including a State, political subdivision of a State, or Indian tribe) directly affected by a requirement of a State, political subdivision or tribe may apply to the Secretary of Transportation for a determination

whether the requirement is preempted. The Secretary of Transportation has delegated authority to PHMSA to make determinations of preemption, except for those concerning highway routing (which have been delegated to the Federal Motor Carrier Safety Administration). 49 CFR 1.53(b).

Section 5125(d)(1) requires notice of an application for a preemption determination to be published in the Federal Register. Following the receipt and consideration of written comments, PHMSA publishes its determination in the Federal Register. See 49 CFR 107.209(c). A short period of time is allowed for filing of petitions for reconsideration. 49 CFR 107.211. A petition for judicial review of a final preemption determination must be filed in the United States Court of Appeals for the District of Columbia or in the Court of Appeals for the United States for the circuit in which the petitioner resides or has its principal place of business, within 60 days after the determination becomes final. 49 U.S.C. 5127(a).

Preemption determinations do not address issues of preemption arising under the Commerce Clause, the Fifth Amendment or other provisions of the Constitution, or statutes other than the Federal hazardous material transportation law unless it is necessary to do so in order to determine whether a requirement is authorized by another Federal law, or whether a fee is “fair” within the meaning of 49 U.S.C. 5125(f)(1). A State, local or Indian tribe requirement is not authorized by another Federal law merely because it is not preempted by another Federal statute. *Colorado Pub. Util. Comm'n v. Harmon*, above, 951 F.2d at 1581 n.10.

In making preemption determinations under 49 U.S.C. 5125(d), PHMSA is guided by the principles and policies set forth in Executive Order No. 13132, entitled

"Federalism" (64 FR 43255 (Aug. 10, 1999)), and the President's May 20, 2009 memorandum on "Preemption" (74 FR 24693 (May 22, 2009)). Section 4(a) of that Executive Order authorizes preemption of State laws only when a statute contains an express preemption provision, there is other clear evidence Congress intended to preempt State law, or the exercise of State authority directly conflicts with the exercise of Federal authority. The President's May 20, 2009 memorandum sets forth the policy "that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption." Section 5125 contains express preemption provisions, which PHMSA has implemented through its regulations.

IV. Public Comments

All comments should be directed to whether 49 U.S.C. 5125 preempts the New Jersey regulations on the transportation of regulated medical waste in commerce. Comments should specifically address the preemption criteria discussed in Part II above.

Issued in Washington, DC on November 7, 2011

/s/ _____
Vanessa L. Allen Sutherland
Chief Counsel

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