New Jersey Regulations on Transportation of Regulated Medical Waste: Notice Of Administrative Determination Of Preemption by the Pipeline and Hazardous Materials Safety Administration on 12/12/2013

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Who, What, When and Why

* Who - The Pipeline Hazardous Materials Safety Administration (PHMSA), which is an agency under the USDOT
* What - 9 of NJDEP Regulated Medical Waste Administrative Codes – N.J.A.C. 7:26-3A were preempted
* When - 12/12/2013
* Why – PHMSA felt that these requirements were not substantively the same as the Hazardous Materials Regulations.
And what gives them the authority?

49 CFR 171.1  Applicability of Hazardous Materials Regulations (HMR) to persons and functions.
Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) directs the Secretary of Transportation to establish regulations for the safe and secure transportation of hazardous materials in commerce, as the Secretary considers appropriate….

49 CFR 173.134 Class 6, Division 6.2
Definition of a regulated medical waste can be found.

**Regulated Medical Waste is a Hazardous Material**
1. N.J.A.C. 7:26–3A.10(a) that generators must separate into different containers before transport sharps, fluids (greater than 20 cc), and other regulated medical waste;
2. N.J.A.C. 7:26–3A.11(d) which allows a generator to ship oversized medical waste without placing it in a packaging as required by the HMR;
3. N.J.A.C. 7:26–3A.14 that the words “Medical Waste” or “Infectious Waste” must be labeled on the outside of the package when there is untreated regulated medical waste;
4. N.J.A.C. 7:26–3A.15 that each “generator shall mark each individual container of regulated medical waste in accordance with all applicable Federal regulations. . . . .” and that the markings must include details of the transporter’s name, the date of shipment, the intermediate handler’s name, and other specific information;
5. N.J.A.C. 7:26–3A.19 and those provisions of 7:26–3A.31 which require the use of a specific “tracking form” to accompany shipments of regulated medical waste that are prescribed for either the generator or the transporter;
6. N.J.A.C. 7:26–3A.28 that, when transferring between transporters, each transporter must place a water resistant tag below the generator’s marking on the outer surface of the container with the transporter’s name, solid waste registration number, and date of receipt; and

7. N.J.A.C. 7:26–3A.30 which requires that a vehicle used to transport regulated medical waste must have: (1) The name of the transporter; (2) the NJDEP solid waste transporter registration number; and (3) either the words “Medical Waste” or “Infectious Waste” on two sides and the back of the cargo-carrying body.

8. N.J.A.C. 7:26–3A.45 to the extent that it requires rail transporters to comply with the transporter requirements of 7:26–3A.28 and 7:26–3A.30.

How does this preemption affect me?

1. N.J.A.C. 7:26-3A.10(a)
Generators do not have to separate their sharps, fluids (greater than 20 cc), and other regulated medical waste into separate containers before transport.

What should I follow?
49 CFR 173.197
Specifically (b), (e)(2), and (e)(3)
What is Non-bulk packaging?
49 CFR 171.8

Non-bulk packaging means a packaging which has:

* (1) A maximum capacity of 450 L (119 gallons) or less as a receptacle for a liquid;
* (2) A maximum net mass of 400 kg (882 pounds) or less and a maximum capacity of 450 L (119 gallons) or less as a receptacle for a solid;
* (3) A water capacity of 454 kg (1000 pounds) or less as a receptacle for a gas as defined in §173.115 of this subchapter; or...
Non-bulk packaging
Bulk packaging means a packaging, other than a vessel or a barge, including a transport vehicle or freight container, in which hazardous materials are loaded with no intermediate form of containment. A Large Packaging in which hazardous materials are loaded with an intermediate form of containment, such as one or more articles or inner packagings, is also a bulk packaging. Additionally, a bulk packaging has:

* (1) A maximum capacity greater than 450 L (119 gallons) as a receptacle for a liquid;
* (2) A maximum net mass greater than 400 kg (882 pounds) and a maximum capacity greater than 450 L (119 gallons) as a receptacle for a solid; or
* (3) A water capacity greater than 454 kg (1000 pounds) as a receptacle for a gas as defined in §173.115 of this subchapter.
Bulk Packaging
(b) Non-bulk packagings. Except as provided in §173.134(c) of this subpart, non-bulk packagings for regulated medical waste or clinical waste or (bio) medical waste must be UN standard packagings conforming to the requirements of part 178 of this subchapter at the Packing Group II performance level. A non-bulk packaging used as a sharps container must be puncture-resistant for sharps and sharps with residual fluid as demonstrated by conducting the performance tests in part 178, subpart M, of this subchapter on packagings containing materials representative of the sharps and fluids (such as sterile sharps) intended to be transported in the packagings. Sharps containers must be securely closed to prevent leaks or punctures in conformance with the instructions provided by the packaging manufacturer in accordance with §178.2(c) of this subchapter.
(2) Liquid regulated medical waste or clinical waste or (bio) medical waste transported in a Large Packaging, Cart, or BOP must be packaged in a rigid inner packaging conforming to the provisions of subpart B of this part. Liquid materials are not authorized for transportation in inner packagings having a capacity greater than 19 L (5 gallons).
(3) Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in part 178, subpart M, of this subchapter at the Packing Group II performance level.
### Where to find Packing Requirements

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49 CFR 173.197

* Rigid
* Leak resistant
* Impervious to moisture
* Burst, tear and break resistant
* Puncture resistant for sharps
* Sealed to prevent leaks
* Meets UN PG II specs of Part 178

N.J.A.C. 7:26-3A.11 Packaging requirements
(b) Generators shall ensure that all regulated medical waste is placed in a containers that are:
1. Rigid;
2. Leak-resistant;
3. Impervious to moisture;
4. Sufficiently strong to prevent tearing or bursting under normal conditions of use and handling; and
5. Sealed to prevent leakage during transport.
How does this preemption affect me?

2. N.J.A.C. 7:26-3A.11(d)
A generator cannot ship oversized medical waste without placing it in packaging as required by the HMR.

PHMSA determined that allowing “oversized regulated medical waste” to be transported without any form of packaging or containment, is in stark contrast to the authorized bulk packagings required in § 173.197. Just as N.J.A.C. 7:26–3A.10(a) was preempted so is N.J.A.C. 7:26–3A.11(d). They both cover the packing, repacking, and handling.
3. N.J.A.C. 7:26-3A.14

The words “Medical Waste” or “Infectious Waste” do not have to be labeled on the outside of a rmw package.
Either “INFECTIOUS SUBSTANCE” must be affixed on packages that contain regulated medical waste or the packaging must be marked with the “BIOHAZARD” marking, see exception under 49 CFR 173.134(c)(1)(i).
Biohazard Marking under OSHA 1910.1030
4. N.J.A.C. 7:26-3A:15

Generators are no longer required to put the following on the outside of the rmw package:
- The generator's name, address, NJDEP RMW generator ID;
- The transporter's name and NJDEP solid waste registration number;
- The date of shipment; and

AND are no longer required to mark the inner containers with
- The generators name and address
What is required under the 49 CFR for marking requirements?

See Part 172, Subpart D and E

- Proper shipping name
- Identification number – UN3291
- Consignor or consignee name and address
- Infectious substance label (or Biohazard label)
- Orientation arrows (if applicable)
The Hazardous Materials Regulations (HMR) require that the inner packagings authorized for large packagings, carts, and bulk outer packagings containing regulated medical waste “must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, Cart, or BOP originates at a single location and is delivered to a single location.” 49 CFR 173.197(e).
(d) **Consignee's or consignor's name and address.** Each person who offers for transportation a hazardous material in a non-bulk package shall mark that package with the name and address of the consignor or consignee **except** when the package is—

1. Transported by highway only and will not be transferred from one motor carrier to another; or
2. Part of a carload lot, truckload lot or freight container load, and the entire contents of the rail car, truck or freight container are shipped from one consignor to one consignee.
5. N.J.A.C. 7:26-3A.19

A generator that transports or offers for transport regulated medical waste for off-site treatment, destruction, or disposal does **NOT** have to use the New Jersey regulated medical waste tracking form.

However, if the generator or transporter chooses to use a NJ RMW Tracking Form they can. The preemption only states that we cannot enforce a specific form to be used.

**How Do I Know If My Form Is Correct If It Is NOT A NJ RMW Tracking Form?**

Refer to 49 CFR, Part 172, Subpart C – Shipping Papers
Part 172.202

Shipping description
* Proper Shipping Name
* Hazard Class/Division
* Identification Number
* Packing Group
* Total Quantity
* Shippers Certification
* Emergency Response Telephone Number
Exceptions to using Shipping Papers

Are there any exceptions???

Who does not have to use/prepare a shipping paper?
**Answer: Materials of Trade (MOTS)**

49 CFR 171.8

*Material of trade* means a hazardous material, other than a hazardous waste, that is carried by a private motor carrier in direct support of a principal business that is other than transportation.
49 CFR 173.6  Materials of trade exceptions.

When transported by motor vehicle in conformance with this section, a material of trade (see §171.8 of this subchapter) is not subject to any other requirements of this subchapter besides those set forth or referenced in this section.

(a) *Materials and amounts*. A material of trade is limited to the following:

(4) A Division 6.2 material, other than a Category A infectious substance,
6. N.J.A.C. 7:26-3A.28
When transferring between transporters, transporter no longer have to place a water resistant tag below the generator's marking on the outer surface of the container with the transporter's name, solid waste registration number, and date of receipt...

Goes back to marking requirements.
See Part 172, Subpart D and E
How does this preemption affect me?

7. N.J.A.C. 7:26-3A.30
Transporter’s name, NJDEP transporter registration number and “Medical Waste” or “Infectious Waste” on two sides and the back of the cargo-carrying body are no longer required.
The solid waste decal must still be displayed on the driver’s side of the vehicle or on any registered piece of equipment.

Federal Motor Carriers Safety Administration (FMCSA) - 49 CFR 390.21 - a commercial motor vehicle that has a gross vehicle weight rating or gross combination weight rating, or gross vehicle weight or gross combination weight, of 4,536 kg (10,001 pounds) or more, whichever is greater must have their company’s name marked on the vehicle.
How should my vehicle be marked?

Refer to:
49 CFR 172.332 Identification number markings
49 CFR 173.134(a)(1)(ii) – regulated medical waste (Category B only) is assigned identification number UN3291.
How should my vehicle be marked?

49 CFR 172.331 (c)
For a bulk packaging contained in or on a transport vehicle or freight container, if the identification number marking on the bulk packaging (e.g., an IBC) required by § 172.302(a) is not visible, the transport vehicle or freight container must be marked as required by § 172.332 on each side and each end with the identification number specified for the material in the § 172.101 table.
How should my vehicle be marked?

49 CFR 172.332 and 172.336 require that vehicles containing **non-bulk packages of a single hazardous materials** with an aggregate gross weight of the hazardous material is 4,000 kg (**8,820 pounds**) or more to be marked with the identification number on either orange panels or on a plain white square-on point display configuration having the same outside dimensions as a placard.
Applies to rail transportation such as marking requirements and the use of a specific tracking form.

Refer to 49 CFR, Part 172, Subpart D and E for marking and labeling requirements.
Refer to 49 CFR, Part 172, Subpart C – Shipping Papers.
What requirements were NOT preempted???

NJDEP can still enforce the following:

1. N.J.A.C. 7:26-3A.21(a)(1)
   To the extent that it requires the generator to retain a copy of the shipping paper for at least three years from the date the regulated medical waste was accepted by the transporter.

2. N.J.A.C. 7:26-3A.21(a)(2)
   To the extent that it requires the generator to retain a copy of any exception report for at least three years after the day the exception report was submitted.

Retention time is still the same, 3 years...
What requirements were NOT preempted???

3. N.J.A.C. 7:26-3A.22
To the extent that it requires the generator of regulated medical waste to **file an exception report** with the state when a transporter and/or destination facility notifies the generator of any discrepancy between the shipment as accepted by the initial transporter and delivered to the destination facility

4. N.J.A.C. 7:26-3A.32
To the extent that it requires the transporter to deliver the entire quantity of regulated medical waste to the proper party listed on the tracking form;
What requirements were NOT preempted???

5. N.J.A.C. 7:26-3A.33
To the extent that does not require a particular form to be used to consolidate the multiple shipments.

They do **not** have to use NJ RMW Tracking form to consolidate a shipment but **must reference the new consolidation tracking form in the original tracking form AND enter the tracking form number of the original tracking form in the consolidation tracking form.** In addition if more than 20 tracking forms are being consolidated, reference shall be made in the consolidation log and enter the total number of tracking forms being consolidated.
6. N.J.A.C. 7:26-3A.34
To the extent that it requires that the transporter of regulated medical waste to retain a copy of the shipping paper for at least three years from the date the regulated medical waste was accepted by the next party.

Retention time is still the same, 3 years...
What requirements were NOT preempted???

7. N.J.A.C. 7:26-3A.41
To the extent that it requires intermediate handlers and destination facilities to certify that they had received the listed regulated medical waste.

PHMSA advised in the Federal Register that they read the intent of 7:26–3A.41 as ensuring that the hazardous materials reach the intended recipient on the shipping document and that these provisions are not preempted.
Where can I get more information?

Federal Register


49 CFR 171

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfr171_main_02.tpl

49 CFR 172

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfr172_main_02.tpl
49 CFR 173
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NJDEP Regulations