



Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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Department of Health and Human Services
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RE: Ebola Preparedness

Dear [REDACTED]

Consistent with my last communication dated October 17, 2014, I forward today additional guidance for your consideration as you continue preparations for evaluating patients for possible Ebola virus disease (EVD).

In ongoing efforts to provide the latest information to healthcare providers and Maine citizens regarding guideline updates and developments regarding preparedness and response to potential suspected cases of Ebola, the Maine Center for Disease Control announced the launch of a new website, www.maine.gov/ebola. The publicly facing website includes descriptions of Ebola, how it is transmitted and other important information about the disease. Easy-to-understand fact sheets and answers to frequently asked questions are also available and can be downloaded. The pages for healthcare providers offer the latest in Federal Centers for Disease Control and Prevention (CDC) guidance on a variety of topics and will serve as a repository of information for those organizations and their staff as well as first responders. Maine CDC's Health Alert Network can also be accessed from this site.

Enclosed you will find procedural guidance from the Federal Department of Transportation describing the requisite packaging of actual or suspected EVD waste materials. Please distribute this guidance to relevant personnel within your organization.

The Federal CDC issued new guidance on October 20, 2014, related to the donning and doffing of personal protective equipment (PPE). Though you probably already have this information, I provide the following link out of an abundance of precaution, which link will direct your personnel to the specific CDC web page where the new guidance is located: <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>.

The CDC has also released interim guidance with regard to treatment of Ebola as a "select agent". Ebola virus is regulated as a "select agent" in accordance with U.S. Department of Health and Human Services Select Agent Regulation (42 CFR Part 73). If live-infectious Ebola virus is confirmed, any diagnostic or clinical specimens (e.g., blood, urine, tissue, and other body fluids) that are kept would be covered by the regulations and would have to be destroyed, decontaminated, or transferred to a registered select agent facility within seven days of notification that live-infectious Ebola virus was detected. The regulations are comprehensive and also describe what specimens and waste materials are not subject to the regulations. Your staff may find the interim guidance at the following link: <http://www.cdc.gov/vhf/ebola/hcp/select-agent-regulations.html>.

Finally, the Department has also been asked by some hospitals about reimbursement concerns/procedures, and whether the Centers for Medicare and Medicaid Services (CMS) have identified special funding for providers who treat patients with actual or suspected EVD. Based on information I have received from CMS, there are no extra funds to pay for services related to EVD treatment other than what beneficiaries (Medicare, Medicaid, and Children's Health Insurance Programs) are normally eligible to receive. For ICD-9, Ebola is coded as 078.89 (Other specified diseases due to viruses). Medicare Part C will pay for all medically necessary services covered by Medicare for eligible Medicare Part C beneficiaries. Medicare Part D will cover all drugs with medically accepted indications for EVD provided in an outpatient setting for eligible Medicare Part D beneficiaries. Medicaid and CHIP reimbursement is appropriate for covering waste management needs, costs associated with isolation of a patient, personal protective equipment and clinical laboratory supplies and equipment. According to CMS, there is no difference in the way a facility would bill for services rendered for EVD compared to other highly infectious diseases with no approved treatments.

Questions regarding EVD surveillance, isolation and treatment may be directed to the Maine Center for Disease Control – Disease Reporting Line at 1-800-821-5821. Questions may also be directed to the relevant Regional Resource Directors: Southern Maine (Paul Weiss) 662-3954; Central Maine (Kara Walker) 795-2960; and Northern Maine (Kathy Knight) 973-8008.

As always, we appreciate your effort to address this public health concern. You can anticipate further guidance from the Department as it becomes available. To that end, and consistent the invitation distributed by Dr. Sheila Pinette yesterday, we will look forward to your participation on a conference call Tuesday, October 28th from 9:30 a.m.-10:30 a.m. The conference call dial-in number is 1-877-455-0244. Enter conference code 6681820529 followed by # (pound sign).

Very truly yours,



Kenneth Albert, RN, Esq.
Director, Division of Licensing and Regulatory Services
Department of Health and Human Services

cc: Mary Mayhew, Commissioner, DHHS
John Martins, Director of Communications, DHHS
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Steven Michaud, President, Maine Hospital Association

Procedural Guidance on the Proper Packaging of Ebola Suspected Waste

DOT Guidance for Preparing Packages of Ebola Contaminated Waste for Transportation and Disposal

This guidance is intended for persons who prepare packages containing waste contaminated or suspected of being contaminated with Ebola, for transportation to off-site treatment and disposal. It provides guidance on DOT regulations regarding the transportation of a Category A infectious substance only and highlights some of the requirements of the HMR, which can affect transportation safety. This document should not be used as a substitute for the HMR to determine compliance.

An infectious substance is regulated as a hazardous material under the U.S. Department of Transportation's (DOT's) Hazardous Materials Regulations (HMR; 49 C.F.R. Parts 171-180). The HMR apply to any material DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce.¹ An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail, or water. Refer to the Center for Disease Control and Prevention (CDC) for guidance on handling these agents before transporting them (see <http://www.cdc.gov/vhf/ebola/hcp/index.html>).

Strict compliance with the HMR is required. For more information on the HMR requirements see <http://phmsa.dot.gov/hazmat/transporting-infectious-substances>. The HMR contains federal requirements for transporting hazardous materials in commerce. If a person requires a variance to the HMR, that person must apply for a Special Permit under 49 CFR § 107.105. DOT may grant a special permit if the applicant can demonstrate that an alternative packaging will achieve a safety level that is: (1) at least equal to the safety level required under the HMR, or (2) consistent with the public interest if a required safety level does not exist.

In addition, the motor carrier, including its driver, must comply with the Federal Motor Carrier Safety Regulations (FMCSR), 49 C.F.R., Parts 300-399, as applicable.

Packaging Preparation: Bag the waste in plastic film bags and place in a rigid outer packaging.

Note: Individual plastic film bags may weigh no more than 10 kg (22 lbs.) when filled. An outer packaging may contain more than one set of triple bagged waste.

Step 1

- Follow all appropriate occupational safety and health requirements in place by regulating agencies and your facility;
- Place the potentially contaminated waste into the first plastic bag;
- Prior to closure, treat potentially contaminated waste with an U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g.,

¹ The HMR applies to interstate, intrastate, and foreign commerce.

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norovirus, rotavirus, adenovirus, poliovirus) that is recommended by the CDC for use as a disinfectant for the Ebola virus. Please review product label to ensure it meets these requirements;

- Place sharps waste in an authorized sharps container, and close and seal it in accordance with the packaging instructions for that container;
- Wrap objects with sharp edges to prevent the tearing or puncture of the plastic bag;
- Close the plastic film bag by tying the bag with a knot or other equally effective positive means of closure that will not tear or puncture the outer bag or liner such as heat sealing, tape, or adhesive, and will ensure any liquid contents will not leak from the packaging; and,
- Disinfect the exterior surface of the plastic bag with an EPA-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) that is recommended by the CDC for use as a disinfectant for the Ebola virus.

Step 2

- Place the first plastic film bag, with the knot facing upward, into a second plastic film bag;
- Close the second plastic film bag by tying the bag with a knot or other equally effective positive means of closure that will not tear or puncture the outer bag or liner such as heat sealing, tape, or adhesive, and will ensure any liquid contents will not leak from the packaging. Make sure the primary bag does not interfere with closing the second bag;
- Disinfect the exterior surface of the second bag with an EPA-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) that is recommended by the CDC for use as a disinfectant for the Ebola virus.

Step 3 – Preparation of outer packaging

- The outer package must be either a rigid UN Standard or DOT Approved non-bulk packaging. If the outer packaging is fabricated from fiberboard, it must be a minimum of triple wall and contain a 6 mil polyethylene liner.
- Place absorbent material sufficient to absorb all free liquid (if any) in the bottom of the rigid outer packaging or the liner of the fiberboard outer packaging;
- Place the double bagged waste into the rigid outer packaging or into the outer fiberboard packaging with an installed liner;
- Close the liner (if used) either by zip tie or other equally effective means of closure or as specified by the manufacturer of the packaging;
- Securely close the outer packaging as specified by the manufacturer of the packaging;
- Disinfect the exterior surface of the package with an EPA-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) that is recommended by the CDC for use as a disinfectant for the Ebola virus.

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Authorized Packaging Materials

Plastic film bag

Plastic film bags must:

- Be 175 liters or smaller (46 gallons);
- Be marked and certified by its manufacturer as having an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag when tested in accordance with ASTM D 1709 and ASTM D 1922;
- Be compatible with the EPA-registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) used to disinfect the waste and packagings.

Outer packaging

The outer packaging must:

- Be a UN Standard or DOT Approved non-bulk packaging:
 - Drums made of plastic, or triple wall corrugated fiberboard (authorized under approval);
or
 - Boxes made of plastic or triple wall corrugated fiberboard;
- Be certified and tested to the PG II level;²
- Have a minimum of a six millimeter polyethylene plastic liner if the outer packaging is fiberboard;
- Must be marked and labeled in accordance with 49 CFR §172.301.

Operational Controls – Medical Facility

- The outer packaging must be closed except when being filled with inner packagings containing waste materials;
- Before loading the package into a transport vehicle, the medical facility must ensure that the package is not leaking and the package is closed and sealed according to the recommended closure instructions.

Operational Controls – Transporter

Note: If the waste contaminated or suspected of being contaminated with Ebola cannot be packaged and transported in accordance with the HMR, the waste transporter may apply for a special permit. The following list of operational controls is provided as guidance for those seeking special permits and should be addressed in the special permit application.

² Will be either an X or Y certified package.

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- Materials may be transported by highway only.
- The motor carrier, including its driver, must comply with the Federal Motor Carrier Safety Regulations (FMCSR), 49 CFR Parts 300-399, as applicable.
- Loading and unloading the vehicle must be performed using manual means. Fork trucks or other powered mechanical handling equipment may not be used for loading or unloading the vehicle.
- After loading and prior to transportation, the transporter must perform an external visual inspection of the transport vehicle to determine that it is closed and free of leakage.
- All shipments must be accompanied by a Hazardous Materials Shipping Paper in accordance with 49 C.F.R. §172 Subpart C.
- While in transportation, the doors on the motor vehicle or shipping container being used to transport the material must be closed and locked except when an outer packaging is being loaded or unloaded into the vehicle.
- The transporter may only transport the vehicle loaded with the material to a final destination that is authorized by applicable laws for treatment or disposal of such materials, without unnecessary delay from the time the carrier's motor vehicle leaves the shipper's premises.
- Waste must be transported to the nearest appropriate disposal facility available at the time the material is offered for transportation without additional loading or unloading of the vehicle.
- The transporter must have a written spill response plan that includes provisions for the decontamination of spilled materials and for personal protective equipment to be carried on the vehicle and used to protect its employees from contact with infectious materials in any form.
- The transporter must respond to any release from a package that occurs during transportation. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the package involved. Any release must be reported to PHMSA as soon as practicable.
- Each motor vehicle used must be decontaminated in accordance with applicable federal, state and local laws.
- Each motor vehicle and driver involved in the transport of the contaminated waste must be made available for a Commercial Vehicle Safety Alliance (CVSA) Level I hazardous materials inspection prior to transport. If violations of the CVSA North American Standard Out-of-Service Criteria (2014 edition) are found, the violation(s) must be corrected prior to transporting hazardous materials.