State of Montana *Health Alert Network*

DPHHS HAN

Health UPDATE

Cover Sheet

DATE: October 5, 2015

SUBJECT: Clarification Healthcare Facilities Using Contractors for Reusable Devices

INSTRUCTIONS:
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For LOCAL HEALTH DEPARTMENT reference only

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Epidemiology Section
1-406-444-0273

DPHHS Health Alert Hotline:
1-800-701-5769

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Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.
Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

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State of Montana ***Health Alert Network***

DPHHS HAN

Information Sheet

Date: October 5, 2015

Subject: CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

Background: CDC is updating a previously released Health Alert Network message.

Information: As part of the original HAN, CDC asked healthcare facilities to verify that third party vendors who perform maintenance and repair on reusable medical devices are "certified." In this clarification, CDC is noting that there are no formal or standardized certification processes for these vendors. They are now asking healthcare facilities to verify that contracted vendors have appropriate training programs.

Recommendations: Please refer to the attached CDC HAN for clarification on this issue.

This is an official

CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
October 2, 2015, 08:00 EST (08:00 AM EST)
CDCHAN-00383

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

As a follow-up to HAN 00382 (distributed September 11, 2015), the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are providing this update to rescind the following recommendation: If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services. We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Summary

On September 11, 2015, CDC issued HAN 00382 alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

After considering feedback from vendors that perform servicing and repair of reusable medical devices, we are amending HAN Advisory 382 to remove the following sentence: "If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services." We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical [1] and semi-critical [2] items and highlight the need for healthcare facilities to review policies and procedures that protect patients.

Recommendations
Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. The following actions should be performed:

Training

- Healthcare facilities should provide training to all personnel who reprocess medical devices.
    - Training should be required and provided:
        - Upon hire or prior to provision of services at the facility
        - At least once a year
        - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle
    - Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.
    - Healthcare facilities should maintain current documentation of trainings and competencies.
    - If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices the healthcare facility uses.
    - Copies of manufacturers' instructions for operating and reprocessing each type of reusable device should be readily available to staff and inspectors. This file should include instructions for use of chemical disinfectants.

Audit and Feedback

- Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:
    - Performing prompt cleaning after use, prior to disinfection or sterilization procedures
    - Using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life)
    - Monitoring sterilizer performance (e.g., use of chemical and biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping)
    - Monitoring automated endoscope reprocessor performance (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)
- Audits should be conducted in all areas of the facility where reprocessing occurs.
- Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.

Infection Control Policies and Procedures

- Healthcare facilities should allow adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying, proper storage, and transport of reprocessed devices.

    - Considerations should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing.
- Healthcare facilities should have protocols to ensure that healthcare personnel can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in a designated area).
- Healthcare facilities should have policies and procedures outlining facility response in the event of a recognized reprocessing error or failure. Healthcare personnel should assess the cause of the error or failure and the exposure event in order to determine the potential risk of infection. The procedure should include how patients who might have been exposed to an improperly reprocessed medical device would be identified, notified, and followed.
- Individuals responsible for infection prevention and reprocessing at the healthcare facility should be consulted whenever new devices will be purchased or introduced to ensure that infection control considerations are included in the purchasing decision as well as subsequent implementation of appropriate reprocessing policies and procedures and to ensure that the recommended reprocessing equipment is available at the healthcare facility.
- Healthcare facilities should maintain documentation of reprocessing activities, including maintenance records for reprocessing equipment (e.g., autoclaves, automated endoscope reprocessors, medical washers and washer-disinfectors, water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying high-level disinfectants were tested and replaced appropriately.
- Healthcare facilities should follow manufacturer recommendations for maintenance and repair of medical devices that are used to perform reprocessing functions as well as medical devices that are reprocessed.

For more information

Examples of relevant guidance include CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf; and guidance from the Association for the Advancement of Medical Instrumentation (AAMI), available at http://www.aami.org/standards/index.aspx. Health care administrators should work with their infection prevention personnel and accreditation organizations to ensure that all recommendations are properly implemented to protect patients and personnel.

Problems with medical device reprocessing should be reported to the FDA's MedWatch Adverse Event Reporting program either online at https://www.accessdata.fda.gov/scripts/medwatch/, by regular mail, or by fax. Download the form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm or call 1-800-332-1088 to request a reporting form, then complete and mail to address on the pre-addressed form, or submit by fax to 1-800-FDA-0178. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

[1] **Critical items** (e.g., surgical instruments) are objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse.
[2] **Semi-critical items** (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) are objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse.

issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

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