The Needlestick Safety and Prevention Act (HR 5178), signed into law on November 6, 2000, was designed to protect the 8 million healthcare workers in the United States from injuries caused by needles and other sharp medical devices. This new federal law authorized the Occupational Safety and Health Administration (OSHA) to revise the bloodborne pathogens standard to require employers to identify, evaluate, and make use of effective, safer medical devices, and applies to any facilities where employees may be exposed to blood or other potentially infectious material, including home care and hospice organizations.

Since publication of the final rule of the bloodborne pathogens standard in December, 1991, a home care or hospice employee’s risk for contracting a bloodborne disease during the course of providing patient care has been significantly reduced. Yet, occupational exposure to bloodborne pathogens from accidental sharps injuries in all healthcare settings has continued to be a serious problem. The exact number of accidental sharps injuries sustained by home care or hospice employees is not known; however, current estimates indicate that 590,000 accidental sharps injuries are sustained annually by healthcare workers in all healthcare settings (OSHA, 1999). This article reviews the historical events behind the legislation and discusses the modifications to the existing bloodborne pathogens standard and their implications for home care and hospice organizations.

Out With the Old
In December 1991, when the final rule for the bloodborne pathogens standard was published, little data on the efficacy of safer devices were available. In addition, the choice of safer devices was limited. The original bloodborne pathogen standards essentially stated that home care and hospice organizations should be evaluating safety devices, but left a great deal of flexibility in whether their use was adopted.

Since then, there has been a substantial increase in the number and assortment of effective safety devices such as needleless systems and sharps with engineered sharps injury protections available to home care, hospice, and other healthcare organizations. Numerous studies have demonstrated that when safety medical devices are part of an overall bloodborne pathogens risk-reduction program, there is a reduction in accidental sharps’ injuries. The Centers for Disease Control and Prevention has estimated that 62% to 88% of the sharps injuries could potentially be...
prevented by the use of safer medical devices, depending on the type of device used and the procedure involved (OSHA, 1999).

**OSHA’s 1999 Compliance Directive**

In 1998, OSHA issued a Request for Information (RFI) on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. A total of 96 healthcare facilities, groups representing healthcare workers, researchers, educational institutions, professional and industry associations, and manufacturers of medical devices provided comments. In November, 1999, based on feedback from the RFI, OSHA issued a revised Compliance Directive (CPL 2-2.44D) for the Bloodborne Pathogens Standard, which clarified OSHA’s position regarding the use of safety devices as a primary means of preventing bloodborne pathogen exposures. The directive provides guidance to OSHA compliance officers when they are inspecting facilities and enforcing the standard.

Since that time, OSHA has cited healthcare facilities for failing to use safety devices. The use of sharps with engineered sharps’ injury protection is not new and actually is now required. OSHA currently has the authority under the bloodborne pathogens standard to require the use of engineering controls, such as safety devices, to reduce risk to workers. The federal Needlestick Safety and Prevention Act now gives OSHA a legislative mandate to require home care and hospice organizations to provide their employees with safety-engineered sharp devices.

**State-OSHA Plans**

Twenty-three states have state-OSHA plans in effect. The revised bloodborne pathogens standard was published in the Federal Register on January 18, 2001. State-OSHA plans will have to revise their corresponding standards within 6 months of that date. State-OSHA plans are required to have regulations that are “at least as effective” as those of federal OSHA. Some states with state-OSHA plans (i.e., California) have already revised their state Bloodborne Pathogens Standard to require the use of safer devices.

**States With Needle Safety Laws**

Seventeen states have passed needle safety laws that recognize the risks from occupational needlestick injuries; some mandate that the new technology available to prevent needlesticks be used by healthcare facilities. These states are listed in Table 1. If a state’s needle safety law requirements exceed the federal law requirements, the home care or hospice organization must comply with the state’s needle safety law requirements as well as the federal requirements.

For example, in several states, the needle safety laws require that needlesticks be reported to a state agency. If a state’s needle safety law has fewer requirements than the federal law, the federal law’s requirements also must be followed. As a guiding principle, the most restrictive law (i.e., either state or federal) must always be followed in practice.

**In With the New**

When the legislators drafted the federal Needlestick Safety and Prevention Act, they incorporated much language and content of OSHA’s November, 1999 compliance directive (CPL 202.44D) regarding requirements for the use of safety devices. As a result, the bill requires healthcare facilities under the federal OSHA to use safety-engineered devices as a primary engineering control to prevent occupational exposures to bloodborne pathogens in the work setting.
Modifications to the Bloodborne Pathogen Standard

The Needlestick Safety and Prevention Act required that the bloodborne pathogens standard be revised. The following is a summary of the standard’s modifications, along with suggested actions to take to meet the new requirements:

**Modification to the Definitions**

The definition of “engineering controls” within the bloodborne pathogen standard now includes additional examples of controls of safer medical devices, such as sharps with engineered sharps injury protections and needleless systems (Needlestick Safety and Prevention Act of 2000, Pub. L. No. 106-430, 114 Stat. 1901 [Nov. 6, 2000]).

The term “Sharps with Engineered Sharps Injury Protections” has been added to the definitions noted within the bloodborne pathogen standard and is defined as:

“A nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident” (Needlestick Safety and Prevention Act of 2000, Pub. L. No. 106-430, 114 Stat. 1901 [Nov. 6, 2000]).

The term “Needleless Systems” was added to the definitions noted with the bloodborne pathogen standard and defined as:

“A device that does not use needles for: the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; the administration of medication or fluids; or any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps” (Needlestick Safety and Prevention Act of 2000, Pub. L. No. 106-430, 114 Stat. 1901 [Nov. 6, 2000]).

**ACTION**

1. Review the home care or hospice organization’s existing exposure control plan and modify the content to reflect the new/modified definitions.

**Modification of the Exposure Control Plan**

Exposure control plans are to be reviewed and updated to:

- reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens, and
- document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure (Needlestick Safety and Prevention Act, 2000).

1. Document the revision to the exposure control plan to reflect the plan and timetable for evaluating, selecting, and implementing safety-engineered devices in all device categories with a potential for bloodborne pathogen exposure.

2. Record the procedure for evaluating and documenting the circumstances surrounding an exposure incident in the exposure control plan.

3. Implement the procedures for documenting and evaluating an exposure incident as identified in the exposure control plan.

**ACTION**

On an annual basis:

1. Document the review of the exposure control plan.

2. As necessary, revise the exposure control plan to reflect changes/updates in commercially

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**TABLE 1**

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<th>States With Needlestick Prevention Legislation</th>
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A detailed description of an individual’s state’s law requirement can be obtained online at: http://www.med.virginia.edu/epinet/statelist.html.
available and effective engineering controls designed to eliminate or minimize exposure.

Even if the home care or hospice organization is providing safety devices, be prepared to defend their effectiveness against the latest devices being introduced; an OSHA compliance officer may want to review that analysis.

**New Sharps Injury Log Requirement**

A home care or hospice organization is now mandated to establish and maintain a sharps injury log to record percutaneous injuries from contaminated sharps, as the previous OSHA 2000 log did not sufficiently reflect injuries that may involve exposure to bloodborne pathogens. The documentation maintained in the sharps injury log must be recorded and maintained in a way that protects the confidentiality of the injured employee. Minimally, the sharps injury log must contain:

1. the type and brand of device involved in the incident,
2. the department or work area where the exposure incident occurred, and
3. an explanation of how the incident occurred (Needlestick Safety and Prevention Act, 2000)

**ACTION**

1. Continue to document on the OSHA 200 log.
2. Collect exposure data on sharp-object injuries and blood and body fluid exposures on separate forms that protect the confidentiality of the injured employee.
3. Document the type and brand of device involved in the incident, the department or work area (location) where the exposure incident occurred, and how the incident occurred, documentation should include the:
   - route(s) of the exposure,
   - engineering controls in use at the time,
   - work practices followed,
   - protective equipment or clothing that was used at the time of the exposure incident,
   - procedure being performed when the incident occurred,
   - employee’s training, and
   - comparison of similar occurrences and recommendations to avoid future exposures.
4. Aggregate the ongoing exposure incident data collected and analyze the data to determine if any adverse patterns or trends were noted.

If an OSHA inspection occurs, copies of the home care and hospice organization’s documentation on exposure incidents will be requested to determine if compliance has been met.

**Solicitation of Input From Nonmanagerial Employees**

A new section added to the bloodborne pathogen standard requires a home care or hospice organization to solicit input from nonmanagerial employees responsible for direct patient care—who are potentially exposed to injuries from contaminated sharps—in the identification, evaluation, and selection of effective engineering and work practice controls. The exposure control plan must document their participation (Needlestick Safety and Prevention Act, 2000).

**ACTION**

Establish a multidisciplinary team that includes clinical management and direct patient care providers potentially exposed to injuries from contaminated sharps to:

1. coordinate the activities of sharps injury prevention program to include the development or revision of a plan for selection, evaluation, and implementation of safety-engineer safety devices and needless systems;
2. gather information on the current use and availability of safety devices;
3. collect data and identify sharps devices in use with the greatest risk of exposure to bloodborne pathogens to be replaced;
4. identify, evaluate, and select safety-engineered sharps devices with protective features that retract, blunt, or otherwise shield the sharp point or edge after use and needless systems;
5. meet with product vendors to identify and choose safety devices to pilot test;
6. pilot-test safety devices for their effectiveness in patient care, reducing injuries, and ease of use;
7. select safety devices to replace targeted devices;
8. educate and train staff on the use of safety devices, needless systems, and safer work practices;
9. replace existing devices with safety devices as soon as possible after training;
10. develop strategies to ensure compliance with the use of safety devices and needless systems;
11. collect data and periodically evaluate the effectiveness of safety devices and needless systems in reducing the risk of injury from...
contaminated sharps and their impact on worker injury rates and patient safety; and
12. document the involvement of direct patient care providers in all activities including: evaluation, selection, and implementation of safety-engineered devices in all device categories.

Exemptions
The modifications to the bloodborne pathogens standard do not mandate that a home care or hospice organization implement the use of any engineering control, including a safer medical device, in any situation where it may jeopardize a patient’s or employee’s safety, or where it may be medically contraindicated. If a home health agency or hospice chooses not to use an available safety device or a device with a safety component, documentation must be maintained that explains why an available safety device(s) was not used and describes how it would have endangered the patient or employee. Many of the new safety devices are considerably more expensive; however, OSHA does not consider cost an acceptable reason for exemption. OSHA expects safety devices to be implemented if they reduce or eliminate occupational exposures to blood.

Following the passage of the bloodborne pathogen standard in 1991, both the dental and home health industries sought exemption from the rule. The American Dental Association v. Martin decision granted a limited exemption to the home care industry (Rhinehart & Friedman, 1999). The court held that OSHA had not adequately considered feasibility problems for home care providers, where employees work at sites that the employer does not control. As a result, OSHA may not cite a home care and hospice organization for site-specific violations such as:

- housekeeping requirements (e.g., maintenance of a clean and sanitary work site),
- handling and disposal of regulated waste,
- ensuring the use of personal protective equipment,
- ensuring that specific work practices are followed (e.g., hands are washed with running water), and
- ensuring the use of engineering controls (e.g., safety devices).

OSHA may cite a home care or hospice organization for failure to comply with all nonsite-specific requirements of the standard such as:

- supplying personal protective equipment for the employee’s use in the home;
- providing safety devices to employees (e.g., sharps with “engineered sharps injury protection,” needleless devices, blunt needles, plastic capillary tubes), and training employees to use the devices properly;
- maintaining and updating the exposure control plan;
- offering hepatitis B vaccinations;
- providing postexposure evaluation and follow-up;
- maintaining a sharps injury log; and
- providing initial and ongoing employee education.

To avoid an OSHA citation related to the use of engineering controls or safety devices, safety devices must be available for the employee’s use in the home and the employee must have received prior training in how to use the devices. The safety devices may be provided to the staff member on an individual basis and stored in the staff’s supply bag taken into the home or the devices may be left in the home for the staff’s use.

Effective Date
The Needlestick Safety and Prevention Act (HR 5178) was signed into law on November 6, 2000. The revised Bloodborne Pathogen standard was published in the Federal Register on January 18, 2001. The standard takes effect 90 days after publication. Thus, the effective date was April 18, 2001.

REFERENCES


CE Test: Occupational Injuries and Needlestick Legislation

General Purpose
These articles describe measures to prevent occupational hazards. Specific safety devices and recommended procedures for phlebotomy and needle disposal are discussed.

Objectives
Read the following articles in this issue: The Impact of the Needlestick Safety and Prevention Act on Home Care and Hospice Organizations by Mary M. Friedman, MS, RN, CRNI, and Guide to Needlestick Prevention Devices by Dennis J. Ernst, MT(ASCP).

Questions
1. Which of these questions should be considered most important when evaluating safety devices for effectiveness?
   a. How long does it take to discard or permanently sheath the needle?
   b. Is the product user friendly?
   c. How much do these safety devices cost?
   d. Will the product enhance patient satisfaction?

2. When evaluating a safety device for phlebotomy you should give high priority to devices:
   a. with two-hand activation.
   b. that will change usual procedures.
   c. with end-to-end protection.
   d. that activate with maximum manipulation.

3. The most effective safety disposal device for used needles:
   a. allows the healthcare worker to remove the needle quickly.
   b. retracts the needle from the patient’s arm into a protective holder.
   c. positions the needle upward after withdrawal from the patient.
   d. provides a puncture-proof cap to be placed over the used needle.

4. In the event that a sharps container is unavailable at your client’s home, you should be prepared to:
   a. immediately wash the used needle.
   b. cover the tip with a tip-seal size cover.
   c. twist the needle off with gloved hands.
   d. place the used needle in an envelope.

5. The contaminated sharps container that meets OSHA standards is one that:
   a. can be easily opened and is reusable.
   b. is stored outside the patient’s room.
   c. puncture resistant and leak proof.
   d. has a needle clip and can be locked.

6. The window of vulnerability refers to the:
   a. time between exposure and developing symptoms.
   b. time between needle removal from the patient and its discard.
   c. immune status of the exposed individual.
   d. virulence of the contaminated organism.

7. Which of these types of venipuncture collection tubes is safest?
   a. glass
   b. mercury based
   c. plastic
   d. laser

8. If a home care agency’s state needle-safety requirements exceed the federal law requirements, it:
   a. can choose which directives to follow.
   b. should develop its own standards.
   c. must comply with both the state and federal mandates.
   d. should adhere to the federal rules.

9. Which of these requirements was included in the Federal Needlestick Safety and Prevention Act?
   a. requirements for the use of safety devices
   b. funding for agency changes
   c. creation of a federal needlestick data base
   d. agency penalties for excusively injuries

10. Which of these changes meets OSHA’s recommended engineering controls standards?
    a. use of needleless systems
    b. mandatory training programs
    c. increased staffing levels
    d. automatic vacuum systems

11. Which of these actions is required annually for a home care agency?
    a. evaluate all sharps-related staff injuries
    b. develop mandatory remedial programs
    c. recreate agency standards and policies
    d. document the review of the exposure control plan

12. Required information to be included in the sharps injury log includes:
    a. the name of the injured employee
    b. the brand of the device involved in the incident.
    c. the names of two witnesses to the incident.
    d. educational training provided after the incident.

13. A home care organization may be cited by OSHA for failure to comply with:
    a. ensuring the use of personal protective equipment.
    b. ensuring that employees wash their hands correctly.
    c. proper disposal of contaminated waste in the home.
    d. offering hepatitis B vaccinations to employees.

14. Which of these practices by a healthcare worker increases the risk for an accidental needlestick?
    a. recapping needles with two hands
    b. drawing blood before wearing gloves
    c. tearing off the tip of your glove to help find a vein
    d. removing the tourniquet with one hand after penetrating the vein

15. Which of these procedures is associated with the highest rate of accidental needlesticks?
    a. drawing blood without gloves
    b. using a syringe to draw blood
    c. applying a tourniquet to locate veins
    d. drawing arterial blood gases

16. Which of these instructions should a nurse educator include when teaching staff safety tips to prevent needlestick injuries?
    a. “The needle should never leave your hand until it is discarded.”
    b. “Always completely fill up the sharps containers.”
    c. “Place contaminated needles on the bedside table, out of the patient’s reach.”
    d. “Remove the needle from the syringe before discarding it.”

17. What is the recommended time interval between removal of the needle from the patient’s arm to permanent discard?
    a. 6 seconds to 5 seconds
    b. 5 seconds to 10 seconds
    c. 10 seconds to 20 seconds
    d. 20 seconds to 30 seconds

Test Responses:

1. Did this CE activity’s learning objectives relate to its general purpose?  Y  N
2. Was the journal home study format an effective way to present the material?  Y  N
3. Was the content current to nursing practice?  Y  N
4. How long did it take you to complete this CE activity? _______ hours
5. Suggestions for future topics _________________________

Lippincott Williams & Wilkins CE Home Study Enrollment Course
Ocupational Injuries and Needlestick Legislation
CE Credit: 2.5 Contact Hours  Fee: $18.75  Registration Deadline: June 30, 2003

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SS# Are you certified?  Yes  No  
Certified by ____________________________ Telephone # ____________________________

Last Name ____________________________ First Name ____________________________ MI _______
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