

**WEST VIRGINIA**

**SECRETARY OF STATE**

**KEN HECHLER**

**ADMINISTRATIVE LAW DIVISION**

Form #4

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**NOTICE OF RULE MODIFICATION OF A PROPOSED RULE**

AGENCY: Division of Health  
Department of Health and Human Resources TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code § 16-36-1

AMENDMENT TO AN EXISTING RULE: YES  NO


IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: \_\_\_\_\_

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 82

TITLE OF RULE BEING PROPOSED: Needlestick Injury Prevention

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

  
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Joan E. Ohl, Secretary

\$4.00

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TITLE 64  
LEGISLATIVE RULE  
DIVISION OF HEALTH  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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STATE OF WEST VIRGINIA

SERIES 82  
NEEDLESTICK INJURY PREVENTION

**§64-82-1. General.**

1.1. Scope – This legislative rule establishes specific standards and procedures concerning needlestick injury prevention; creates a needlestick injury prevention program in hospitals, nursing homes, public health departments and home health agencies, including those staffed by public employees; makes compliance with rules a condition of licensure; establishes requirements for facilities to use needleless systems; relates to keeping sharps injury logs; requires the maintainment of a list of existing needleless systems; sets forth exceptions to requirements; and other matters pertinent and necessary for the implementation of the Needlestick Injury Prevention Program, W.Va. Code §16-36-1 et seq. This rule supplements the Needlestick Injury Prevention Program, W.Va. Code §16-36-1 et seq., and should be read in conjunction with the Act.

1.2. Authority. – W.Va. Code §16-36-2.

1.3. Filing Date. –

1.4. Effective Date. –

**§64-82-2. Application and Enforcement.**

2.1. Application – This rules applies to:

2.1.a. Every hospital licensed under the provisions of WV Code §16-5B-1 et seq.;

2.1.b. Every nursing home licensed under the provisions of WV Code §16-5C-1 et seq.

2.1.c. Every local health department;

2.1.d. Every home health agency certified by the office of health facility licensure and certification;

2.1.e. All hospitals and nursing homes operated by the state or any agency of the state; and

2.1.f. All hospitals, nursing homes, local health departments and home health agencies which are staffed in whole or in part by public employees.

2.2. Enforcement – This rule is enforced by the director of the division of health or his or her lawful designee.

### **§64-82-3. Definitions.**

3.1. Annual Report. -- A quality improvement report, submitted to the director on a yearly basis, including a summary of trends in needlestick injuries and suggestions as to whether or how protective mechanisms or work practice control could be utilized to prevent the injuries.

3.2. Contaminated. -- The presence or the reasonably anticipated presence of blood or other potentially infectious materials on a surface or in or on an item.

3.3. Engineered Sharps Injury Protection.

3.3.a. A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms; or

3.3.b. A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

3.4. Engineering Controls. -- Sharps prevention technology including, but not limited to, systems not using needles and needles with engineered sharps injury protection that isolate or remove the bloodborne pathogens hazard from the workplace.

3.5. Exposure incident. -- A specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

3.6. HBV. -- Hepatitis B virus.

3.7. HCV. -- Hepatitis C virus.

3.8. HIV. -- Human immunodeficiency virus.

3.9. Occupational Exposure. -- Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

3.10. Protective Equipment. -- Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be protective equipment.

3.11. Quarterly Report. -- A quarterly supplement to the annual report, reported to the director, containing the specific information of each exposure incident as set forth in section five of this rule and a cover sheet with patterns of needlestick and sharps injuries that the facility has identified.

3.12. Sharps. -- Any object used or encountered by a health care worker that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, hollow-bore needles or sharp instruments, including, but not limited to, needles, lancets, and scalpels.

#### **§64-82-4. Use of needleless systems or other engineering controls.**

4.1. Facilities shall use needleless systems for:

4.1.a. Withdrawal of body fluids after initial venous or arterial access is established;

4.1.b. Administration of medications or fluids; and

4.1.c. Any other procedure involving the potential for an exposure incident for which a needleless system or other engineering control is available as an alternative to the use of needle devices.

4.1.d. Facilities are not required to use a needleless system:

4.1.d.1. In cases where the facility can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure;

4.1.d.2. In circumstances where the technology is medically contraindicated or where the facility demonstrates by means of objective product evaluation criteria that the use of the technology is not more effective than alternative measures used by the facility to prevent exposure incidents;

4.1.d.3. In cases where the employer shows that no needleless systems or engineered sharps injury protection devices are available in the marketplace for a medical procedure because of limits in supply or in technology;

4.1.d.4. In circumstances in which the employer shows that sufficient information is not available on safety performance of needleless systems or sharps devices with engineered protection available in the marketplace and the employer is actively evaluating the devices;

4.1.d.5. In circumstances in which health care employees involved in patient 's care determine, in the reasonable exercise of their clinical judgement, that use of the engineering control will jeopardize the patient's safety or the success of a medical nursing procedure involving the patient.

4.2. If needleless systems are not used, needles with engineered sharps injury protection shall be used for:

4.2.a. Withdrawal of body fluids;

4.2.b. Accessing a vein or artery;

4.2.c. Administration of medications or fluids; and

4.2.d. Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.

4.3. If sharps other than needle devices are used, these items shall include engineered sharps injury protection.

#### **§64-82-5. Sharps Injury Log.**

5.1. A facility shall record information concerning exposure incidents in a sharps injury log, to be kept within the facility, which shall include:

5.1.a. The date and time of the exposure incident;

5.1.b. The type and brand of sharp involved in the incident if known; and

5.1.c. A complete description of the exposure incident including the following information:

5.1.c.1. The job classification of the exposed worker;

5.1.c.2. The department or work area where the exposure incident occurred;

5.1.c.3. The procedure or task that the exposed worker was performing at the time of the incident;

5.1.c.4. How the incident occurred;

5.1.c.5. The body part involved in the exposure incident;

5.1.c.6. If the sharp had engineered sharps injury protection, whether the protective mechanism was activated and whether the injury occurred before the protective mechanism was activated, during activation of the mechanism, or after activation of the mechanism, if applicable; and,

5.1.c.7. Any suggestions by the injured employee as to whether or how protective mechanisms or work practice control could be utilized to prevent the injuries.

5.2. The sharps injury log shall not contain any personal identifiers, including, but not limited to, the injured employee's name, age, date of birth, social security number, or address.

### 5.3. Recording; Reporting.

5.3.a. The facility shall record the exposure incident on the log within six working days of the date the incident is reported to the employer.

5.3.b. The facility shall prepare an annual report of needlestick injuries within the facility, to be reported to the director, including a quality improvement report based on the data from the quarterly reports. The quality improvement report shall include a summary of trends in needlestick injuries and suggestions as to whether or how protective mechanisms or work practice control could be used to prevent these injuries.

5.3.c. Facilities shall supplement the annual report with quarterly reports to be submitted to the director within thirty days of the close of each quarter. The quarterly reports shall contain the specific information of each exposure incident as set forth in section five of this rule and any patterns of needlestick and sharps injuries that the facility has identified.

5.3.d. The reports required by this rule may be made electronically in a manner approved by the director, or in a form stipulated by the director.

**§64-82-6. List of Needleless Systems and Needles with Engineered Injury Protections.**

6.1. The division of health shall maintain a list of existing needleless systems and needle and sharps with engineered injury protection. The director shall make the list available to assist employers in complying with the requirements of the standards adopted under W.Va. Code §16-36-1 et seq. and this rule. The division of health shall review and update the list annually.

6.2. The list may be developed from existing sources of information, including but not limited to, the federal Food and Drug Administration, the federal Centers for Disease Control, the National Institute of Occupational Safety and Health, and the United States Department of Veterans Affairs.

6.3. Characteristics of needles and sharps with engineered injury protection shall include but not be limited to:

6.3.a. Devices that provide a barrier between the hands and the sharp after use;

6.3.b. Devices that allow or require the health care employees' hands to remain behind the sharp at all times;

6.3.c. An engineering control mechanism that is an integral part of the device and does not need to be added for use;

6.3.d. Devices that are simple and self evident to operate and require little or no training for effective use;

6.3.e. An engineering control mechanism that either requires no activation by the user, or has a safety feature can be engaged with a single-handed technique and allows the worker's hands to remain behind the exposed sharp;

6.3.f. A device that enables the user to easily tell whether the safety feature is activated;

6.3.g. Devices that perform reliably;

6.3.h. Devices that are easy to use and practical;

6.3.i. Devices that are safe and effective for patient care; and

6.3.j. An engineering control mechanism that is integrated with the sharp

after use and remains in effect after disposal to protect health care employees.

#### **§64-82-7. Training.**

7.1. Facilities shall provide a training program to all health care employees who are at risk for occupational exposure which they shall participate in during working hours at no cost to the health care employees.

7.2. The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

7.3. The training shall take place at the time of implementation of a new device and during initial hire orientation of all applicable employees.

7.4. The needlestick injury prevention advisory committee shall set forth specific guidelines and recommendations for the specific areas that the training shall cover.

7.5. The facility shall maintain records of the training of health care employees for three years from the date on which the training occurred or according to facility policy whichever is more stringent.

#### **§64-82-8. Vaccinations.**

8.1. The employer shall ensure that all health care employees who have declined to accept hepatitis B vaccination be offered a hepatitis vaccination series annually thereafter.

8.2. If a routine booster dose of hepatitis B or other vaccines for HCV or HIV are recommended by the U.S. Public Health Service at a future date, the employer shall make the booster dose or vaccination series available to the health care employee at no cost.

#### **§64-82-9. Protective Equipment.**

9.1. All health care employees shall use appropriate protective equipment when occupational exposure can be reasonably anticipated.

9.2. Facilities shall provide appropriate protective equipment to their health care employees at no cost.

#### **§64-82-10. Placement of Sharps Containers.**

Sharps disposable containers should be strategically located and placed so as to be easily visible and to avoid overfilling; they should be within easy horizontal reach of the user. Systems should have secure locking and enable easy replacement. When containers are fixed to a wall, the vertical height should allow the worker to view the opening or access to the container.

**§64-82-11. Confidentiality; Disclosure.**

11.1. No person who obtains information under W.Va. Code §16-36-1 et seq and this rule may disclose information to any other person except for the fulfillment of purposes consistent with W.Va. Code §16-36-1 et seq and this rule.

11.2. Any person who obtains information protected by the provisions of W.Va. Code §16-36-1 et seq and this rule shall sign a statement that he or she fully understands and will maintain the confidentiality of the information.

11.3. The reports of all needlestick injuries submitted in compliance with this rule are protected and are exempt from public disclosure under the exemption for medical records contained in W.Va. Code §29B-1-1 et seq., the Freedom of Information Act: Provided, That the reports are subject to the provisions of W.Va. Code §16-3C-1 et seq. This information shall not be used except as is necessary to enforce State public health laws and rules and to analyze the magnitude of needlestick injuries in the State for assisting in the development of adequate safeguards against their occurrence.

**§64-82-12. Distribution of Rule.**

The division and health care professional licensing boards and agencies may distribute this rule to any facility that has a duty under this rule.

**§64-82-13. Violations and Sanctions.**

13.1. Facilities shall comply with the requirements of the standards adopted under W.Va. Code §16-1-18 and this rule as a condition for licensure, certification, and permission to operate.

13.2. The director may revoke or suspend a facility's licence, certificate, or permission to operate when the facility fails to comply with this rule and all applicable provisions in W.Va. Code §16-36-1.

**§64-82-14. Administrative Due Process.**

Those person adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests, or privileges shall do

so in a manner prescribed in the division of health Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.