

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

JUL 14 12 02 PM '00

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

RULE TYPE: Legislative 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 RULE BEING PROPOSED: 82

TITLE OF RULE BEING PROPOSED: Needlestick Injury Prevention

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON August 15, 2000 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Beth Marquart, Director
Office of Regulatory Development
Department of Health and Human
Resources
Building 3, Room 265
Capitol Complex
Charleston, West Virginia 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

Joan E. O'Neil
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

\$5.00

BRIEF SUMMARY OF THE RULE

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.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

This proposed rule is to ensure that all licensed hospitals, nursing homes, public health departments, and home health agencies, including those staffed by public employees, take appropriate steps toward minimizing the risk of needlestick and sharps injuries to health care workers as required by W.Va. Code §16-36-1. Compliance with this rule is a condition of licensure, certification, or operation.

According to the National Institute for Occupational Safety and Health, somewhere between 600,000 and 800,000 needlestick injuries occur annually among health care workers in the United States. About half of these injuries go unreported. This rule takes significant steps toward minimizing the risk of needlestick and sharps injuries to health care workers within the state of West Virginia. The sharps injury log will provide an effective way to monitor trends in needlestick and sharps injuries within the state and will assist in identifying ways in which to reduce such injuries. The maintainment of a list of needleless systems and other engineering controls will assist facilities in their implementation and utilization of such systems. The use of these systems will in turn dramatically reduce the number of needlestick injuries that health care workers incur.

The proposed rule also sets forth additional requirements, including training, the use of personal protective equipment, and the strategic placement of sharps containers, that are consistent with the purpose of minimizing the risk of needlestick and sharps injuries to health care workers.

Rule Title: Needlestick Injury Prevention, 64CSR82

Copies of the proposed rule will be distributed to all licensed hospitals, nursing homes, home health agencies, and public health departments in West Virginia and to the West Virginia Hospital Association, the West Virginia Medical Association, the West Virginia Nurses Association, the West Virginia Academy of Family Physicians, and the West Virginia Society for Osteopathic Medicine.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Needlestick Injury Prevention, 64CSR82

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: West Virginia Department of Health and Human Resources
Bureau for Public Health

Address: 350 Capitol Street, Room 702
Charleston, WV 25301-3712

Contact Person: Henry G. Taylor, M.D., M.P.H. (304) 558-2971

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$68,618	\$62,118	\$62,118
Personal Services			39,437	39,437	39,437
Current Expense			25,681	22,681	22,681
Repairs & Alterations					
Equipment			3,500		
Other					
Revenue					

2. Explanation of above estimates:

The above estimates reflect the funding through General Revenue to the West Virginia Department of Health and Human Resources approved by the Legislature associated with the implementation of a needlestick injury prevention program, including the costs associated with the establishment and maintainment of a state data system of reported sharps injuries. (See attached)

3. Objective of these rules:

- a. To minimize the risk of needlestick and sharps injuries to health care workers.
- b. To establish a needlestick injury prevention program.
- c. To require facilities to utilize needleless systems or other engineering controls designed to prevent needlestick or sharps injuries.
- d. To establish a sharps injury log to track sharps injury patterns and identify effective ways to minimize those injuries.

Rule Title: Needlestick Injury Prevention, 64CRS82

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

State hospitals and any other agencies of the state which are staffed in whole or in part by public employees would be required to provide the personnel necessary to record and report sharps and needlestick injuries to the division. These facilities would also be required to purchase and utilize needleless systems or other engineering controls designed to prevent needlestick or sharps injuries and provide training to all health care workers who are at risk for occupational exposure as set forth under W.Va. Code §16-36-1.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.


Hospitals, local health departments, home health agencies, nursing homes, and any agencies of the state which are staffed in whole or in part by public employees would be required to provide the personnel necessary to record and report sharps and needlestick injuries to the division. These facilities would also be required to purchase and utilize needleless systems or other engineering controls designed to prevent needlestick or sharps injuries and provide training to all health care workers who are at risk for occupational exposure as set forth under W.Va. Code §16-36-1.

C. Economic Impact on Citizens/Public at Large.

There may be a small increase in health care costs if hospitals and other facilities allocate the costs of implementing the needlestick injury prevention program to their patients or their insurers.

Date: July 14, 2000

Signature of Agency Head or Authorized Representative



Joan E. Ohi, Secretary
Department of Health and Human Resources

Rule Title: Needlestick Injury Prevention, 64CSR82

Breakdown of Estimated Total Cost of Proposed Rule

PERSONAL SERVICES

Data Analyst II	28,000
Administration Fee	205
Retirement @9.5%	2,660
FICA @7.65%	2,142
Workers Comp. @ 6.55%	1,834
PEIA	<u>4,596</u>
	39,437

CURRENT EXPENSES

Travel	15,385
Office Rent	1,546
Office Supplies	600
Printing	1,200
Software Support	5,000
Telephone	1,200
Postage	<u>750</u>
	25,681

EQUIPMENT

Computer Equipment	<u>3,500</u>
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TOTAL **68,618**

FILED

JUL 14 12 05 PM '00

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

64CSR82
TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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 §16-36-1.

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 article five-b of this chapter;

2.1.b. Every local health department;

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

2.1.d. All hospitals and nursing homes operated by the state; and

2.1.e. Any agency of the state and 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 such 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 utilize 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 is available as an alternative to the use of needle devices.

4.1.d. Exceptions shall include:

4.1.d.1. 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. 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. 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; or

4.1.d.4. 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.

4.2. 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 protections 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. Information concerning exposure incidents shall be recorded in a sharps injury log, to be kept within the facility, and 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; 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 such injuries.

5.2. The sharps injury log shall not contain any personal identifiers, including, but not limited to, 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 utilized to prevent such 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 format 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 protections. 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 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 workers' 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 the 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 downstream employees.

§64-82-7. Training.

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

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.

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 workers for seventy-five years from the date of birth.

§64-82-8. Vaccinations.

8.1. The employer shall ensure that all employees who have declined to accept hepatitis B vaccination be offered hepatitis vaccination series within ten days following training provided in §64-82-7 of this rule.

8.2. If a routine booster dose(s) of hepatitis B or other vaccines for HCV or HIV are recommended by the U.S. Public Health Service at a future date, such booster dose(s) or vaccination series shall be made available at no cost to the employee.

§64-82-9. Protective Equipment.

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

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

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

Strategic location and placement of sharps disposable containers should consider ease of visibility to avoid overfilling and 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 failure to comply with this rule and all applicable provisions in W.Va. Code §16-36-1 has occurred.

§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.