

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

Division of Health

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

CITE AUTHORITY W. Va. Code § 16-36-1

AMENDMENT TO AN EXISTING RULE: YES _____ NO X

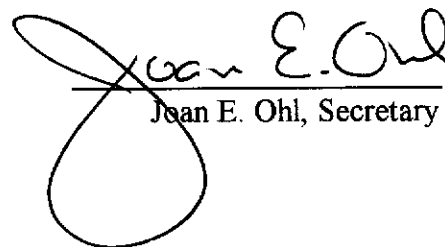
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 82

TITLE OF RULE BEING PROPOSED: Needlestick Injury Prevention

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Joan E. Ohl, Secretary

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 maintenance 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.

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.

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.

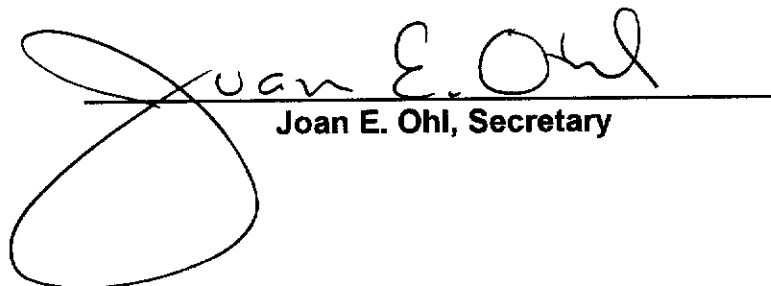
Hospitals, local health departments, home health agencies, nursing homes, and any agencies of the state which are staffed in whole or in part by public employees would be required to provide the personnel necessary to record and report sharps and needlestick injuries to the division. These facilities 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: August 29, 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**

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August 30, 2000

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Division of Health
Department of Health and Human Resources
State Capitol Complex, Building 3, Room 201, Charleston, WV 25305
Telephone: (304) 558-5598

LEGISLATIVE RULE TITLE: Needlestick Injury Prevention

1. Authorizing statute(s) citation: WV Code §16-36-1

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
July 14, 2000

b. What other notice, including advertising, did you give of the hearing?
Notice of the proposed rule was sent to the Needlestick Injury Prevention Advisory Council, the WV Hospital Association, and hospital infection control personnel among others.

c. Date of Public Hearing(s) or Public Comment Period ended:
August 15, 2000

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X

No comments received

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

 August 30, 2000

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

 Beth Marquart, Director

 Office of Policy, Education and Regulatory Support - DHHR

 Building 3, Room 201, State Capitol Complex

 Charleston, West Virginia 25305

- g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

 Loretta Haddy, Director

 Division of Surveillance and Disease Control

 350 Capitol Street, Room 125

 Charleston, West Virginia 25301-3715

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general description of the issues to be decided.

 N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

FILED

64CSR82

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

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**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 nursing home licensed under the provisions of article 5c of this chapter.

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; and

2.1.f. 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 or other engineering control 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.

4.1.d.5 Circumstances in which health care workers are involved in patient 's care determines, in the reasonable exercise of 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 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 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 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 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 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 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 workers 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 employees who have declined to accept hepatitis B vaccination be offered a hepatitis vaccination series annually thereafter.

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.

PUBLIC COMMENTS AND DEPARTMENT RESPONSES

NEEDLESTICK INJURY PREVENTION, 64CSR82

A public comment period on the proposed rule, Needlestick Injury Prevention, 64CSR82, was held beginning on July 14, 2000 and ending August 15, 2000. Comments were received from 21 individuals and/or groups. Comments are summarized below, and the Department's responses and changes to the rule are detailed.

§1.1 et. seq. Comment: It is costly for facilities to comply with these standards.

Response: The Department agrees that implementing needleless systems and needles with engineered sharps injury protection can be costly. However, it is much more costly for a facility to properly respond to cases of sharps injury and the potential exposure of a health care worker to bloodborne pathogens. In addition, it is anticipated that the price of needleless systems will dramatically decrease within the next several years.

§2 Comment: Application and Enforcement - Suggested addition of Emergency Medical Services personnel.

Response: Emergency Medical Services (EMS) personnel are addressed in Legislative Rule 64CSR64 in regards to protective measures when having experienced a bloodborne pathogen exposure. Also, to include them in this rule goes beyond the intent of the language of the statute which cannot be done. Therefore, the Bureau will propose an amendment to the statute for the 2001 Legislative session to include employers of EMS and any other employers of health provider services so that they may be provided needleless devices.

§2.1. Comment: The way this section is worded, only nursing homes that are operated by the state or staffed by public employees are included.

Response: The statement has been clarified and changed to include all nursing homes licensed under the provisions of W.Va. Code §16-5b.

§2.1.a. Comment: House Bill 4298 includes "every nursing home licensed under the provisions of article five-c of this chapter" in its definition of "facility." Under Section 64-82-2 of the proposed rule, that is left out of the entities to which the rule applies. Was this intentional or accidental?

Response: It was an accidental oversight and the rule will be corrected to add "every nursing home licensed under the provisions of article five-c of this chapter".

§4.1. Comment: Blunt suture needles are recommended for reducing employee injury, but this type of suture needle is not safe or suitable for use on certain body tissue (e.g. vascular, intestinal, etc.)

Response: In 64CSR82, exceptions to the use of needleless systems or other engineering controls include circumstances in which technology does not promote employee or patient safety or interferes with a medical procedure.

§4.1. Comment: It is not good teaching practice to use a needle with a protection device when a patient is being instructed on its proper usage. Most patients who administer injections to themselves have little or no need for protective devices.

Response: This rule was intended for prevention of needle stick injuries for employees of the specific facilities defined in the performance of their duties. We will add language in 64-82-4.1.d. Exceptions to include circumstances where patient education is involved for injections to themselves.

§5.1.b. Comment: Need to add, if applicable, the type and brand of sharp involved in the accident.

Response: We will add the words "if known" after the word incident.

§5.3.c. Comment: It is too cumbersome for a nursing home to develop quarterly reports. Annual reports would be sufficient.

Response: The Department understands the labor intensive steps that are necessary to develop quarterly reports. However, in order to develop an effective needlestick injury prevention program in which the Department is able to identify areas of high-risk and actively reduce the incidence of sharps injuries within the state, quarterly reports are needed.

§5.3.d. Comment: May need to add to the rule that there will be a standard reporting form for annual and quarterly reports developed through the advisory committee.

Response: This was the intent of 64CSR82 - 5.3.d with the language..."in a format stipulated by the director". We changed this language to read..."form stipulated by the director."

§6.1 Comment: Recommendation was made that the following be added: Quarterly and annual reports submitted by health care facilities shall be summarized by the director and mailed within 30 days to individuals responsible for Employee Health in their facility. This analysis and reporting of surveillance data permits recognition and prompt intervention with use of appropriate safety products. The surveillance data submitted to the director is collected with a guarantee that the information reported shall not disclose the name of the individual institution, shall be held in strict confidence, shall be used only for the purposes stated, and shall not otherwise be disclosed or released without the consent of the individual or the institution.

Response: A report will be distributed. This is covered in 64-84-11 and strict confidence will be maintained.

§7.3 Comment: In addition to time of implementation of a new device we need to add at orientation (initial hire) for all applicable employees.

Response: Point well taken, the correction will be made for all applicable employees.

§7.5. Comment: It is unreasonable to require the training records to be maintained for seventy-five years from the date of birth of the health care worker. Three years is OSHA's Bloodborne Pathogen requirement.

Response: The seventy-five year requirement for the maintainment of training records was obtained from West Virginia Division of Personnel. The Department was treating these training records as a personnel record. In light of this comment, the rule has been changed to be in compliance with the OSHA regulations. Training records shall be maintained for three years from the date on which the training occurred, or according to facility policy whichever is more stringent.

§7.5 Comment: Would like to change this to read - shall maintain records of the training of health care workers according to hospital policy.

Response: Has already been changed to include this language.

§7.5 Comment: Maintaining records for "seventy-five years from the date of birth" is extensive and burdensome. OSHA requires medical records to be maintained for 30 years post employment. As needlestick injuries are maintained in the employee's medical records, it would be appropriate to use this standard.

Response: Same (as other 7.5 responses.)

§7.5 Comment: It is probably a typographical error but the rule reads: *The facility shall maintain records of the training of health care workers for seventy-five years from the date of birth.* Please review this section.

Response: Same (as other 7.5 responses.)

§8.1. Comment: Vaccinations - At present under The Standard for Bloodborne Pathogens, the employer is required to offer the hepatitis B vaccine to all employees who have occupational exposure, within 10 working days of initial assignment. It also states that if an employee initially declines the vaccination that it shall be made available at a later date if the employee decides to accept the vaccine. Requiring the employer to ensure that all employees who have declined to accept the hepatitis B vaccination be offered the vaccine series within 10 days after the safety device training is redundant and would put an additional burden on those already maintaining the employee health and training records. Therefore, it is suggested adding a statement under §64-82-7., 7.4 that the need for hepatitis vaccination and the availability of such be reinforced at the time of training.

Response: Your comment is well taken. The needlestick injury legislation requires that these legislative rules, 64CSR82, be written in compliance with recent OSHA guidelines. It was the Department's intent to do just that with this statement. OSHA recommends that health care workers who initially decline hepatitis B vaccine at the time of employment be offered such vaccine at a future time, however it does not say specifically when this should be done. Therefore, the legislative rule was written to comply with Chapter 16, Article 36, Section 2, when it recommends that hepatitis B vaccine be offered within 10 days following training provided in Section 64-82-7 of this rule. Since OSHA does not say when this is to occur the needlestick injury rules as required by the law is attempting to state when that offer should be made.

§8.1. Comment: This statement is unclear in meaning. Is a written declination needed each time?

Response: The statement has been clarified. §8.1. has been modified to require hepatitis B vaccination to be offered annually to all employees who have previously declined vaccination.

§8.1. Comment: Due to a two week turn around time for Hepatitis B testing in the State lab, it will be difficult to initiate Hepatitis B vaccine within the ten day requirement.

Response: The ten day requirement has been dropped.

§10. Comment: Placement of Sharps Containers: NIOSH has published a guide to placement of containers that may be appropriate to reference. Please clarify "Systems should have secure locking and enable easy replacement". Is the locking referring to a

locked in place holder? If so, how are free standing units in secure bases and containers in IV baskets viewed?

Response: This language was taken directly from the 2000 APIC state-of-the-art report.

§13.1. Comment: If a physician fails to comply with the proper usage and activation of protective devices on scalpels, will the facility or the practicing physician be held responsible?

Response: Holding a health care worker liable or responsible when an injury occurs as a result of the usage of a needleless system or other safety device goes beyond the scope of the legislative intent of this rule.

§13.2. Comment: If a facility is found to be non-compliant with any requirement under this rule, would the facility be allowed a period of time to correct violation before director would revoke or suspend license?

Response: Yes, it will be discussed further at the August 24, 2000 Needlestick Injury Prevention Advisory Committee meeting.

REVISIONS FOR 64CSR82, NEEDLESTICK INJURY PREVENTION

§64-82-2. Application and Enforcement.

2.1. Application - This rule applies to:

2.1.a. Every hospital licensed under the provisions of W.Va. Code §16-5b;

2.1.b. Every nursing home licensed under the provisions of W.Va. Code §16-5c;

2.1.c. Every local health department;

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

2.1.e. All hospitals and nursing homes operated by the state or 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.

§64-82-4. Use of needless systems or other engineering controls.

4.5.d.1. was added for clarification as follows: Circumstances in which health care workers are involved in patient's care determines, in the reasonable exercise of 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.

§64-82-7. Training.

7.5. The facility shall maintain records of the training of health care workers for three years from the date on which the training occurred.

§64-82-8. Vaccinations.

8.1. The employer shall ensure that all employees who have declined to accept hepatitis B vaccination shall be offered this vaccination series within ten days following each training on the proper usage of needleless systems and devices with engineered sharps injury protection as provided under §64-82-7 of this rule. Each time a health care worker declines to accept hepatitis B vaccinations following training, a written declination of acceptance must be signed by the health care worker and maintained with the training records.



CABELL HUNTINGTON HOSPITAL

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

Dear Ms. Marquart:

I am writing in response to the recently distributed draft copy of 64CRS82, legislative rules for Needlestick Injury Prevention. I have following 3 comments:

I recommend the following be added to Section 64-82-6 on page 5 under #6.1:
Quarterly and annual reports submitted by health care facilities shall be summarized by the director and mailed within 30 days to individuals responsible for Employee Health in their facility. This analysis and reporting of surveillance data permits recognition and prompt intervention with use of appropriate safety products. The surveillance data submitted to the director is collected with a guarantee that the information reported shall not disclose the name of the individual institution, shall be held in strict confidence, shall be used only for the purposes stated, and shall not otherwise be disclosed or released without the consent of the individual or the institution.

Comment #2

House Bill 4298 includes "every nursing licensed under the provisions of article five-c of this chapter" in its definition of "facility." Under Section 64-82-2 of the proposed rule, that is left out of the entitles to which the rule applies. Was this intentional or accidental?

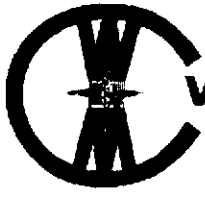
Comment #3:

House Bill 4298 only addresses the need for an annual report containing information from the "sharps injury log," not the quarterly report defined in Section 3.11 and required by section 5.3.c.

I appreciate your consideration of these recommendations/comments.

Sincerely,

Barbara Jones, RN, MSN, CIC
Infection Control Nurse
Cabell Huntington Hospital



WEIRTON MEDICAL CENTER

601 COLLIERS WAY WEIRTON, WV 26062-5091 304-797-6000

August 14, 2000

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

Dear Ms. Marquart:

In reference to 64CSR82, Needlestick Injury Prevention, section §64-82-7., 7.5., to require the maintaining of training records for 75 years is unreasonable. At present, OSHA only requires training records to be kept three years and medical records be kept for at least the duration of employment plus 30 years in accordance with 29CF1910.20, *The OSHA Handbook 2nd Edition*, Brenda Goodner, RN, MSN, CS, Skidmore - Roth, p. 214, 1997. Therefore, taking into consideration the standards required by OSHA already in force and in an effort to prevent an additional burden of record keeping, I recommend changing the proposed rule from 75 years to 3 years.

Section §64-82-8., 8.1. Vaccinations - At present under The Standard for Bloodborne Pathogens (*The OSHA Handbook, 2nd Edition*, Brenda Goodner, RN, MSN, CS, Skidmore - Roth, p. 211, 1997), the employer is required to offer the hepatitis B vaccine to all employees who have occupational exposure, within 10 working days of initial assignment. It also states that if an employee initially declines the vaccination that it shall be made available at a later date if the employee decides to accept the vaccine. Requiring the employer to ensure that all employees who have declined to accept the hepatitis B vaccination be offered the vaccine series within 10 days after the safety device training is redundant and would put an additional burden on those already maintaining the employee health and training records. Therefore, I suggest adding a statement under §64-82-7., 7.4. that the need for hepatitis vaccination and the availability of such be reinforced at the time of training.

Sincerely,

Lisa Schneider, MT, BSN, CIC
Infection Control/Employee Health Coordinator

LS:ch

cc: R. Nolan
D. Wiegmann

cc: Loretta



**Charleston Area
Medical Center**

Post-It™ brand fax transmittal memo 7671		# of pages ▶ 1
To <i>Beth MARQUART</i>	From <i>L. Morris</i>	
Co.	Co. <i>CAMC</i>	
Dept.	Phone # <i>348-9478</i>	
Fax #	Fax # <i>348-8891</i>	

August 15, 2000

Beth Marquart, Director
 officer of Regulatory Development
 Department of Health and Human Resources
 Building 3, Room 265, Capitol Complex
 Charleston, WV 25303

RE: 64CSR82 - Needlestick Injury Prevention

Dear Director Marquart:

Thank you for the opportunity to comment on the draft rule being developed by the WV Department of Health and Human Resources Needlestick Injury Prevention Advisory Committee". I have reviewed the draft and offer the following comments for consideration:

Setn. 7.5: maintaining records for "seventy-five years from the date of birth" is extensive and burdensome. OSHA requires medical records to be maintained for 30 years post employment. As needlestick injuries are maintained in the employee's medical records, it would be appropriate to use this standard.

64-82-10: Placement of Sharps Containers: NIOSH has published a guide to placement of containers that may be appropriate to reference.

Please clarify "Systems should have secure locking and enable easy replacement". Is the locking referring to a locked in place holder? If so, how are free standing units in secure bases and containers in IV baskets viewed?

I would encourage the committee to provide specific forms that will assure standardization of information being reported.

Sincerely,

Lillian D. Morris

Lillian D. Morris, RN, MS
 Safety Director



United to Improve
 America's Health™

WV Needlestick Injury Prevention Law
(64crs82)

- §64-82-2 **Application & Enforcement**
{The way it is written, does not include most nursing homes, only those operated by the state or which are staffed by public employees.}
- 2.1.c Should include nursing homes here? OR
2.1.d Is operated the correct term?
 Or should the term be “licensed” instead of “operated”?
- §64-82-5 **Sharps Injury Log**
5.3.c Quarterly reporting to the state seems too much for nursing home purposes. Exposure incidents are examined in detail per OSHA Bloodborne Pathogens regulations. Annual reporting along with the quality improvement report would probably be adequate, especially for those facilities that have comprehensive safety programs that include quality improvement measures.
- §64-82-7 **Training**
7.5 To require the training records to be kept for so long is unreasonable and would be very cumbersome to manage. OSHA’s Bloodborne Pathogen regulation for training is only 3 years, which is very manageable. (Exposure records are kept for 30 years.)
- §64-82-8 **Vaccinations**
8.1 Somewhat unclear as to when a facility must offer vaccine – within 10 days after initial training, after annual bloodborne pathogens training, after training for any new devices? Do we have to get a written declination each time?



West Virginia Health Care Association

8 CAPITOL STREET, SUITE 700
CHARLESTON, WV 25301-2896
TELEPHONE (304) 346-4575
FACSIMILE (304) 342-0519

August 8, 2000

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

Dear Beth,

In my review of series 82, needlestick injury prevention legislative rule which is out for public comment, I found on page 7 article 7.5, something of concern. It is probably a typographical error but the rule reads: *7.5. The facility shall maintain records of the training of health care workers for seventy-five years from the date of birth.* Please review this section.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mike Hay', written over a horizontal line.

Mike Hay
Dir. Reimbursement &
Government Relations
e-mail MHay1@Citynet.net

c. Dana Moyers, Legislative Committee Chair

Post-It® Fax Note	7671	Date	7/24/00	# of pages	3
To	Loretta Haddy	From	Jael Fulton		
Co./Dept.	State Epi.	Co.	QA NURSE BHHF		
Phone #		Phone #	558-6480		
Fax #	558-6335	Fax #	558-2230		

MEMORANDUM

To: Loretta Haddy, M.A., M.S.
State Epidemiologist

From: Jael Fulton, R.N. JAF
Quality Assurance Nurse - BHHF

Date: July 24, 2000

Subject: Needlestick Injury Prevention - Legislative Rule

I am attaching the comments of two state facilities regarding the submitted Legislative Rule on Needlestick Injury Prevention.

I believe Ms. Dunn's comments refer to sections §64-82-7. Training. 7.1 versus §64-82.8. Vaccinations. 8.1 where the ten (10) day period to offer the vaccination is specified. Ms. Dunn is the DON of Bateman Hospital in Huntington, WV.

If you have questions please feel free to contact me or the specific parties.

Jael Fulton - Needle stick prevention

Page 1

From: Becky Dunn
To: Jael Fulton
Date: Tuesday, July 18, 2000 9:53AM
Subject: Needle stick prevention

Our IC RN has reviewed the draft on the needle stick prevention. Our only concern is that we use the State lab for all of our Hep B screens. The turn around time for those results is over 2 weeks. So we would not be able to initiate Hep B vaccine until those results are back. Thanks.

CECIL H. UNDERWOOD
Governor

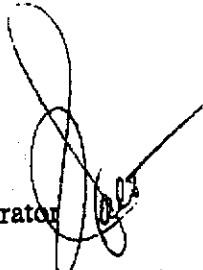


WALTER J. GARRETT
Administrator

State of West Virginia
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

July 14, 2000

TO: Jael Fulton, RN

FROM: Walter J. Garrett, Administrator 

RE: Comments/Concerns Title 64: Legislative Rule-Needlestick Injury prevention

Concerns:

1. Facility expense to comply with standards.
2. Physician compliance with proper usage and activation of protective devices on scalpels. Who will be held responsible for non-compliance? Facility or the practicing physician.
3. Under §64-82-13 Violations and Sanctions: 13-2. If facility found to be non-compliant with any requirement under this rule, would facility be allowed a period of time to correct violation before director would revoke or suspend license?

Comments:

1. Blunt suture needles are recommended for reducing employee injury, but this type of suture needle is not safe or suitable for use on certain body tissue (example - vascular, intestinal, etc).



Pleasant Valley Home Health Services

Home Health • Private Duty • Hospice

August 1, 2000

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

Re: Comment on Needle-stick Injury Prevention
Proposed Legislative Rule, Title 64, Series 82

Dear Ms. Marquart,

This letter is to provide comment on proposed legislative rule, Title 64, Series 82, Needle-stick Injury Prevention. Compliance with the proposed rule may be unrealistic for home health agencies with regards to the use of needles with sharps injury protection devices.

When a service is being provided by agency staff these devices can be utilized without fail. However, when a patient is being instructed- for instance a diabetic patient being taught self insulin administration- it would not be good teaching practice to use a needle with a protection device when the patient will not be purchasing that type when he or she is independent and the agency is no longer involved.

Any equipment used in teaching should look the same as what the patient will continue to use. While the agency staff can recommend that patients use needles with sharps injury protection devices, use of these devices cannot be mandated. The patient who is self injecting is only at risk of exposure to his or her own blood or body fluids; therefore it is reasonable to assume that the patient will purchase the most cost effective equipment available.

It is my opinion that home health agencies should be expected to use needles with sharps injury protection devices when the patient or caregiver will not be expected to learn the procedure. When the patient or caregiver are learning the procedure, staff should use sharps that the patient will continue to use when agency involvement has ended.

Thank You,
Jane Staley RN
Jane Staley, RN
Home Health Team Leader

1011 Viand Street
Point Pleasant, WV 25550
(304) 675-7400
Fax: (304) 675-7401

CC: Loretta

Pocahontas Memorial Hospital

**R. R. 2 Box 52W
Buckeye, WV 24924
304 - 799-7400
Fax 304 - 799-6636**

August 11, 2000

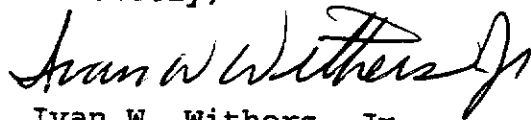
Beth Marquart, Director
Office of Regulatory Development
Department of Health and Human Resources
Building 3, Room 265, Capitol Complex
Charleston, WV 25305

Dear Ms. Marquart:

Thank you for the opportunity to submit our comments on the needlestick injury prevention ruling issued by the legislature. We are very aware of the need for safety in this area, and we only hope that the vendors will make the systems affordable to hospitals, regardless of size. In reviewing the legislative rule, the only section that seemed unreasonable was Section 64-82-7, Training, under 7.5, "The facility shall maintain records of the training of health care workers for seventy-five years from the date of birth." The time period seemed to be excessive.

Thank you again for the opportunity to submit our input.

Sincerely,



Ivan W. Withers, Jr.
Administrator

IWW/rjg

GOOD SHEPHERD NURSING HOME
159 EDGINGTON LANE
WHEELING, WV 26003
PHONE: 242-1093
FAX: 242-1121

RECEIVED
JUL 31 2000
STAFF DEVELOPMENT
& TRAINING

July 28, 2000

Ms. Beth Marquart, Director
Office of Regulatory Development
DHHR
Building 3, Room 265 Capitol Complex
Charleston, WV 25305

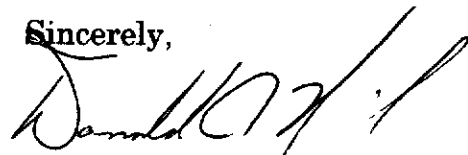
Dear Ms. Marquart:

Thank you for the opportunity to comment on the proposed rule concerning
Needlestick Injury Prevention.

I forwarded the draft rule to our director of nursing and our quality
assurance nurse for review. Enclosed, please find their comments.

Once again that you for the opportunity to comment.

Sincerely,



Donald R. Kirsch
Administrator

Enclosure