THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

JUN 4 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (SAF/MI)

SUBJECT: Policy Letter on Needlestick Safety for Health Care Workers

Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials are a serious concern for health care workers. Newer, safer medical devices can reduce the risk of needlesticks and the chance of contracting deadly bloodborne diseases including human immunodeficiency virus (HIV), hepatitis B virus, hepatitis C virus and others. The Needlestick Safety and Prevention Act, Public Law 106-430, signed November 6, 2000, mandated specific revisions of the Occupational Safety and Health Administration Bloodborne Pathogens standard (29 CFR 1910.1030) with an effective date of April 18, 2001. This revision was intended to ensure widespread use of safer medical devices to prevent dangerous needlesticks.

Effective immediately, it is Department of Defense policy that Medical and Dental Treatment Facilities will comply with newly revised OSHA 29 CFR Part 1910 and all applicable state regulations with respect to needlestick safety. All decisions concerning safety devices will be coordinated with the Regional Tri-Service Product Standardization Boards. The Clinical Product Teams for needlestick safety devices should include employees representing the range of exposure situations encountered in the workplace. The Services will include information on any cost increases associated with this policy in their quarterly product standardization report to the TRICARE Management Activity.

I am confident that adherence to this guidance will afford our healthcare providers greater protection against deadly and debilitating bloodborne diseases. I request you direct immediate implementation within your Service and provide a copy of your implementation instructions to my office.

My point of contact is Gail Sanftleben, Deputy Director for Medical Logistics, at (703) 681-0039, and email, Gail.Sanftleben@tma.osd.mil.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

HA POLICY: 0000013

PCDocs No.: 22590/22604
Due Date:

April 10, 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

THROUGH: H. James T. Sears, M.D., Executive Director, TMA

FROM: Gail Sanftleben, POD, HS&OS, (703) 681-0039

SUBJECT: Policy Letter on Needlestick Safety

DISCUSSION: Needlesticks and other percutaneous injuries resulting in exposure to blood and other potentially infectious material are a serious concern for healthcare workers. The Center for Disease Control estimates more than 800,000 needlestick injuries occur to healthcare workers in the U.S. each year. These workers are at risk for exposure to bloodborne pathogens such as the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV). Recent changes to Occupational Health and Safety Administration standards require increased emphasis on the prevention of needlesticks to include use of safer medical devices. The Services will require additional resources to achieve this standard. Product decisions must be based upon the safety of our employees rather than product costs. The Tri-Service Logistics Chiefs recommend the product standardization decisions and associated costs be documented by the regional Tri-Service Product Standardization Boards.

RECOMMENDATION: The ASD (HA) sign the policy letter.

COORDINATION:

Director, Dental Ops — 4/10/01
Director, Clin Ops — Medical Director 4/10/01 NOT for D Cohen 4/10/01
Director, HS&OS — 4/10/01
TMA OGC — 4-24-01
Dep Dir, (POD) — 4/25/01
Director (POD) — 4/25/01
Chief of Staff (TMA)
DeD TMA
Chief of Staff (HA)

Public Law 106–430
106th Congress

An Act

To require changes in the bloodborne pathogens standard in effect under the Occupational Safety and Health Act of 1970.

Nov. 6, 2000
[H.R. 5178]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Needlestick Safety and Prevention Act.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Needlestick Safety and Prevention Act".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Numerous workers who are occupationally exposed to bloodborne pathogens have contracted fatal and other serious viruses and diseases, including the human immunodeficiency virus (HIV), hepatitis B, and hepatitis C from exposure to blood and other potentially infectious materials in their workplace.

(2) In 1991 the Occupational Safety and Health Administration issued a standard regulating occupational exposure to bloodborne pathogens, including the human immunodeficiency virus, (HIV), the hepatitis B virus (HBV), and the hepatitis C virus (HCV).

(3) Compliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work.

(4) Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March 2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings. Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens, such as HIV, HBV, or HCV.

(5) Since publication of the bloodborne pathogens standard in 1991 there has been a substantial increase in the number and assortment of effective engineering controls available to employers. There is now a large body of research and data concerning the effectiveness of newer engineering controls, including safer medical devices.

(6) 396 interested parties responded to a Request for Information (in this section referred to as the "RFI") conducted

by the Occupational Safety and Health Administration in 1998 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. Comments were provided by health care facilities, groups representing healthcare workers, researchers, educational institutions, professional and industry associations, and manufacturers of medical devices.

(7) Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.

(8) In March 2000, the Centers for Disease Control and Prevention estimated that, depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices.

(9) The OSHA 200 Log, as it is currently maintained, does not sufficiently reflect injuries that may involve exposure to bloodborne pathogens in healthcare facilities. More than 98 percent of healthcare facilities responding to the RFI have adopted surveillance systems in addition to the OSHA 200 Log. Information gathered through these surveillance systems is commonly used for hazard identification and evaluation of program and device effectiveness.

(10) Training and education in the use of safer medical devices and safer work practices are significant elements in the prevention of percutaneous exposure incidents. Staff involvement in the device selection and evaluation process is also an important element to achieving a reduction in sharps injuries, particularly as new safer devices are introduced into the work setting.

(11) Modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.

SEC. 3. BLOODBORNE PATHOGENS STANDARD.

The bloodborne pathogens standard published at 29 CFR 1910.1030 shall be revised as follows:

(1) The definition of "Engineering Controls" (at 29 CFR 1910.1030(b)) shall include as additional examples of controls the following: "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems".

(2) The term "Sharps with Engineered Sharps Injury Protections" shall be added to the definitions (at 29 CFR 1910.1030(b)) and 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".

(3) The term "Needleless Systems" shall be added to the definitions (at 29 CFR 1910.1030(b)) and defined as "a device that does not use needles for: (A) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (B) the administration of medication or

fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps".

(4) In addition to the existing requirements concerning exposure control plans (29 CFR 1910.1030(c)(1)(iv)), the review and update of such plans shall be required to also—

(A) "reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens"; and

(B) "document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure".

(5) The following additional recordkeeping requirement shall be added to the bloodborne pathogens standard at 29 CFR 1910.1030(h): "The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum— Records.

"(A) the type and brand of device involved in the incident,

"(B) the department or work area where the exposure incident occurred, and

"(C) an explanation of how the incident occurred.". The requirement for such sharps injury log shall not apply to any employer who is not required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 and the sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(6) The following new section shall be added to the bloodborne pathogens standard: "An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial 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 and shall document the solicitation in the Exposure Control Plan.".

SEC. 4. EFFECT OF MODIFICATIONS.

The modifications under section 3 shall be in force until superseded in whole or in part by regulations promulgated by the Secretary of Labor under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) and shall be enforced in the same manner and to the same extent as any rule or regulation promulgated under section 6(b).

SEC. 5. PROCEDURE AND EFFECTIVE DATE.

(a) PROCEDURE.—The modifications of the bloodborne pathogens standard prescribed by section 3 shall take effect without regard to the procedural requirements applicable to regulations promulgated under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) or the procedural requirements of chapter 5 of title 5, United States Code.

(b) EFFECTIVE DATE.—The modifications to the bloodborne pathogens standard required by section 3 shall—

(1) within 6 months of the date of the enactment of this Act, be made and published in the Federal Register by the Deadline. Federal Register, publication.

Secretary of Labor acting through the Occupational Safety and Health Administration; and

(2) at the end of 90 days after such publication, take effect.

Approved November 6, 2000.

LEGISLATIVE HISTORY—H.R. 5178:

CONGRESSIONAL RECORD, Vol. 146 (2000):
Oct. 3, considered and passed House.
Oct. 26, considered and passed Senate.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 36 (2000):
Nov. 6, Presidential statement.

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