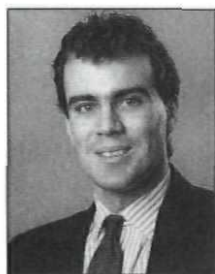


PROTECTING WORKERS FROM PATHOGENS

Employers Must Act Now to Comply With OSHA's New Standard on Bloodborne Pathogens

BY CHRISTOPHER L. WHITE, JD



Mr. White is a healthcare attorney for Gardner, Carton & Douglas, Washington, DC.

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) published its final regulations aimed at reducing workers' occupational risks of infection from bloodborne pathogens. The regulations went into effect on March 6, 1992. The U.S. Department of Labor estimates that the regulations will affect more than 5.6 million workers and could prevent nearly 200 deaths and 9,000 bloodborne infections annually. The regulations require healthcare employers to implement sweeping new controls in record keeping, engineering, hazard prevention, and work practice, as well as other worker protections.

A NEW OSHA STANDARD

The regulations declare a new "standard" under the Occupational Safety and Health Act (29 U.S.C. Sections 651 *et seq.*). The new standard

represents the most pervasive regulation OSHA has imposed on healthcare entities. The regulations represent the culmination of several years of work by OSHA and others involving numerous written comments and submissions and live testimony of more than 400 people representing healthcare providers, labor, and other interested groups at five public hearings.

An OSHA standard is an individual set of legal rules designed to minimize a certain category of on-the-job risks to workers. (For example, separate OSHA standards govern worker exposure to benzene, cotton dust, and various carcinogens.) A violation of any one of the rules in the bloodborne pathogen standard can result in the same type of citation and carries the same penalties as a violation of any other OSHA standard.

OSHA establishes standards only after much analysis and circumspection. The act authorizes the secretary of labor to set mandatory safety and

Summary A new standard set forth by the Occupational Safety and Health Administration (OSHA) requires healthcare employers to implement sweeping new controls in areas such as record keeping, engineering, hazard prevention, and work practice. Through the bloodborne pathogen standard, which went into effect on March 6, OSHA acknowledges that healthcare workers face significant health risks as a result of occupational exposure to blood and other infectious materials.

Although most prudent healthcare providers already adhere to the Centers for Disease Control's universal precautions, the OSHA regulations include several additional mandatory measures that are more specific and stringent. The additional measures include the development of an exposure control plan, procedures for responding to an

employee's exposure to bloodborne pathogens, the implementation of certain engineering and work practice controls to eliminate or minimize on-the-job exposure risks, and the provision of personal protective equipment and information and training programs.

OSHA estimates that the greatest cost component of implementing procedures to bring a facility into compliance is attributable to the purchase of personal protective equipment. Although the costs of compliance are substantial, OSHA has estimated that these costs represent less than 1 percent of the healthcare industry's annual revenues.

Violation of the bloodborne pathogen standard may result in penalties of up to \$70,000, depending on the severity of the infraction. Criminal penalties are also possible for willful violations that result in worker death.

health standards to ensure safe and healthful workplaces for American workers. However, the Supreme Court has ruled that before OSHA issues a new standard, it must make two threshold findings:

- That a place of employment is unsafe in that significant work-related risks are present

- That the risks can be eliminated or reduced by a change in

practices (*AFL-CIO v. American Petroleum Institute*, 448 U.S. 601 [1980])

Through the bloodborne pathogen standard, OSHA acknowledges that healthcare workers face significant health risks as the result of occupational exposure to blood and other infectious materials. The risk arises because such materials are common in many healthcare workplaces and may contain infectious bloodborne pathogens such as the hepatitis B virus (HBV), the human immunodeficiency virus (HIV), the syphilis spirochete, the malaria parasite, and other pathogenic microorganisms. Although OSHA found insufficient published data to quantify the risks of HIV infection relative to *all* healthcare workers, it specifically concluded that for every 1,000 career *research and production laboratory workers* with occupational exposure, approximately 195 will become HIV positive as a result of occupational exposure, over a 45-year career. The agency further concluded that the combination of controls and precautions set forth in the standard could prevent about 8,400 to 8,800 HBV infections each year.

BREADTH OF COVERAGE

The OSHA standard applies to all occupational exposure to blood and other potentially infectious materials. The term "occupational exposure" is defined as any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially dangerous materials that may result from the performance of an employee's duties. The term "blood" encompasses human blood, blood components, and products made from human blood. Other potentially infectious materials included within the

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scope of the regulations include:

- Human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, any body fluid that is visibly contaminated with blood, and all mixtures of body fluids in which it is difficult or impossible to differentiate between body fluids

- Any unfixed tissue

or organ (other than intact skin) from a living or dead person

- HIV-containing cell or tissue cultures and organ cultures; HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from animals infected with HIV or HBV for experimental purposes

STANDARDS OF COMPLIANCE

The OSHA regulations mandate that all employers subject to the standard observe the Centers for Disease Control's (CDC's) universal precautions. Universal precautions require healthcare workers to consider all patients as potentially infected with HIV or other bloodborne pathogens and to adhere to strict preventive measures, such as the use of gloves and other protective barriers, to minimize the risk of exposure to such blood and body fluids. Although most prudent healthcare providers already use universal precautions, the OSHA regulations include several additional mandatory measures that are more specific and stringent.

Exposure Controls The bloodborne pathogen standard mandates two means of exposure control. First, each employer having workers who may be at risk for occupational exposure to blood or other infectious materials must develop an exposure determination. The determination must contain (1) a list of all job classifications, including employees at risk for occupational exposure, (2) a list of job classifications, including employees with *some* risk for occupational exposure, and (3) a list of exposure-prone tasks performed by employees in the above job classifications.

Employers included within the regulations' scope are required to develop an exposure control

plan to eliminate or minimize worker exposure to bloodborne pathogens. The plan must feature at least the following three elements:

- The exposure determination
- The schedule and means of implementing the regulations' other requirements (e.g., postexposure vaccine and follow-up, record keeping, communication of hazards)
- The procedure for employer evaluation of exposure incidents

At a minimum, the plan is to be updated annually and to be made accessible to employees and the secretary of labor. Employers' exposure control plans must be completed by May 5, 1992.

Postexposure Evaluation and Treatment With limited exceptions, the standard requires employers to make the hepatitis B vaccine and vaccination series available to all employees at risk for occupational exposure. A licensed healthcare professional must vaccinate the employee at the employer's expense within 10 working days of initial assignment to the exposure-prone job.

After an exposure incident, the OSHA standard requires that exposed employees be tested to determine whether in fact an infection has been transmitted, and it further provides for mandatory follow-up treatment and counseling of infected workers. Any employee involved in an exposure incident is entitled to:

- Disclosure of the routes of exposure and the circumstances under which exposure occurred
- Disclosure of the identity of the source individual, unless prohibited by state law or unless identification is impossible
- The results of the source individual's blood tests, subject to local laws regarding consent
- Counseling to modify behavior
- A healthcare professional's written opinion and evaluation of the worker's health status resulting from the exposure
- Safe and effective postexposure prophylaxis and hepatitis B immune globulin injections

Work and Engineering Controls The standard mandates that employers implement certain engineering and work practice controls to eliminate or minimize on-the-job exposure risks. For example,

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employers must have hand-washing facilities readily accessible to employees and must ensure that employees wash their hands immediately after the removal of personal protective equipment (PPE) and immediately after contact with infected materials.

OSHA believes that easy access to hand-washing facilities would increase the likelihood of use and minimize the possibility of

contamination. For those situations, where sinks and running water cannot be made available for hand washing, such as in ambulances, OSHA has accepted in principle that alcohol wipes or other hand-washing substitutes may be used until exposed workers are able to wash their hands. However, OSHA emphasizes that hands must be washed at the earliest possible time after use of the alternative methods.

Employers further must store, maintain, or discard sharps and contaminated material only in accordance with the regulations' technical packaging, labeling, and handling rules.

Personal Protective Equipment Where there is an on-the-job risk of exposure, the employer must provide, at no cost, appropriate PPE such as gloves, gowns, laboratory coats, face shields or masks, eye protection, mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Under normal conditions of use, appropriate PPE does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing or skin.

In addition, the employer must ensure that employees use PPE at all times, except for extraordinary circumstances where the employee briefly and temporarily declines use in a specific instance in which, in the employee's judgment, use would have prevented the delivery of healthcare or would have posed an increased hazard to the worker or a co-worker. Employers must launder and dispose of PPE as specified under the house-keeping standard (described below).

Hazard Communication The OSHA standard requires employers to affix labels bearing the fluorescent orange or orange-red biohazard symbol to all containers used to store or transport blood or

potentially infectious materials. Contaminated equipment must be similarly labeled. Regulated waste that has been decontaminated, as well as blood and blood components that have been released for clinical use, are exempt from the labeling rules.

Information and Training

The regulations state that an employer must pay for a training program for employees who are at risk of occupational exposure to bloodborne pathogens. The training must take place within 90 days after the effective date of this standard and at least annually thereafter. Newly assigned workers must receive training at the time of initial assignment to tasks where occupational exposure may occur. At a minimum, the training program must include:

- An accessible copy of the regulatory text of the bloodborne standard
- An explanation of the epidemiology and symptoms of bloodborne diseases
- An explanation of transmission modes
- An explanation of the employer's exposure control plan
- An explanation of how to recognize tasks that may pose an on-the-job risk of exposure
- An explanation of risk-limitation methods (e.g., PPE, work and engineering controls)
- Information on the use, handling, removal, and disposal of PPE
- An explanation of how to select appropriate PPE for specific tasks
- Information on the hepatitis B vaccine
- Protocol for emergencies involving blood or potentially infectious material
- Protocol for exposure incidents
- Information regarding postexposure evaluation and follow-up
- An explanation of the signs and labels required by the regulations
- An opportunity to question and receive answers from the person conducting the training session

Record Keeping The regulations require employers to establish and maintain accurate medical records for each employee with occupational

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exposure, including vaccination, testing, examination, and follow-up data. The employer must retain the records for the duration of the worker's employment, *plus 30 years*. The employer must ensure the records are kept confidential. For three years, employers must maintain training records, including attendance records, summary of training sessions, and names and qualifications

of instructors. All employees at risk of occupational exposure to HBV who decline a vaccination must complete a written declination.

Housekeeping As a rule, employers must provide a clean and sanitary workplace. All environmental and working surfaces must be decontaminated immediately after contact with blood or other infectious materials, and employers must implement written schedules for regular cleaning and decontamination. Regulated waste, including laundry, contaminated sharps, and other materials, is to be maintained, treated, and packaged in accordance with the stringent practices set forth in the regulations. The protocol requirements include the use of sealed, labeled, and color-coded containers and disposal in accordance with other state and federal laws.

ESTIMATED COSTS OF COMPLIANCE

Although the actual costs of complying with the OSHA regulations vary with each type of facility affected, the characteristics of exposure, and the degree of each facility's current compliance, OSHA estimates that the total annual cost of compliance is approximately \$813 million. The greatest component of these costs is attributable to the purchase of PPE (\$327 million). Training, vaccination, and postexposure follow-up and housekeeping are among the most significant cost components.

OSHA estimated the following annual costs per facility:

Physicians' offices	\$ 1,179
Nursing homes	5,719
Hospitals	51,946
Medical laboratories	2,784

Residential care facilities	\$1,798
Home health agencies	1,778
Hospices	911

Although the costs of compliance are indeed substantial, OSHA has estimated that these costs represent less than 1 percent of the healthcare industry's annual revenues and has concluded that most of the compliance costs would be passed along to consumers and third-party payers as a result of the strong and inelastic demand for healthcare services.

Although many healthcare facilities observe universal precautions and therefore already should achieve partial compliance with the standard, some industry observers have stated that the OSHA estimates appear somewhat low. In any event healthcare providers will not welcome the extra expenditures that will arise as a result of the standard. Healthcare providers are already facing increasing cost-containment pressures from government and consumers.

PENALTIES FOR NONCOMPLIANCE

Violation of the bloodborne pathogen standard (or any other OSHA safety or health standard) may result in penalties of up to \$70,000, depending on the severity of the infraction. Criminal penalties (including prison terms) are also possible for willful violations that result in worker death. However, OSHA's calculation of a penalty for a particular violation is a complicated and subjective process.

Under the Occupational Safety and Health Act, OSHA is authorized to conduct inspections and to issue citations and proposed penalties for alleged violations of OSHA standards. Except for employee complaints, most violations come to OSHA's attention when OSHA compliance officers conduct routine administrative inspections. OSHA's legal authority for inspections is broad; compliance officers may enter and inspect a workplace during normal working hours within "reasonable" limits and in a "reasonable" manner (29 C.F.R. Section 1903.3 [1991]). If the compliance officer discovers any violation during the inspection, the employer will receive either a citation or a notice of *de minimis* violation, based on the facts and circumstances of the violation. A *de minimis* violation is one that has no direct or immediate relationship to worker safety or health. On the other hand, a citation is issued for a violation that affects worker health or safety; a citation may result in civil penalties and an order requiring abatement of the danger.

For the purpose of assessing civil penalties, the act categorizes citations as "serious," "other than serious," or "willful." A serious violation indicates substantial probability that death or serious physical harm could result. An organization found guilty of a serious violation will be assessed a penalty of up to \$7,000 for each occurrence [29 U.S.C. Sections 666(b), (k) (1991)]. An organization found guilty of an infraction considered to be "other than serious" may be fined \$7,000; however, a penalty is not mandatory for this type of violation. Employers that fail to correct the infraction for which a citation is issued may be assessed a penalty of up to \$7,000 for each day the violation continues. Willful or repeated violations are subject to a civil penalty of up to \$70,000, with a mandatory fine of at least \$5,000 for "willful" violations [29 U.S.C. Section 666(a) (1991)].

The ultimate assessment to be imposed also is subject to the discretionary application of certain adjustment factors, which could decrease the severity of a penalty. Such factors could apply to employers who make good faith efforts to reach compliance, to small employers, to relatively minor violations, or to entities with no previous OSHA violations. The potential penalties that could be imposed, however, are substantial and are not to be disregarded.

EFFECTIVE DATES

Although the effective date for the new OSHA standard was March 6, 1992, some components of the standard have individual effective dates. Exposure control plans must be completed by May 5, 1992; the record keeping and information-training provisions go into effect June 4, 1992; and the engineering and work practice controls, PPE, HBV vaccination, postexposure follow-up, and certain hazard communication requirements are scheduled to be effective July 6, 1992.

UNRESOLVED ISSUES AND FURTHER GUIDANCE

Independent Contractors One important unresolved issue is how the standard applies to independent contractors. Because, under a strict reading, the standard states that the protective obligations extend only to employees, the status of other workers is unclear. As with other OSHA standards, however, the Department of Labor undoubtedly will focus on who is in the best position to evaluate, control, or correct the hazard and cite that individual or entity. Moreover, some of the requirements of the standard (e.g.,

waste labeling and disposal) expressly place the burden of compliance on the healthcare facility vis-à-vis other persons who may come into contact with the hazard.

In addition, OSHA personnel have indicated that the issue of the independent contractor may be addressed in a future national directive to be released by OSHA's central office. Directives are issued to assist OSHA

compliance officers in the enforcement of OSHA standards. A national directive is expected to be distributed to the regional offices to clarify other issues as well. However, at press time OSHA officials could not predict when the national directive would be issued. Until issuance of the national directive, healthcare facilities are cautioned against assuming that they are not responsible for protecting independent contractors under the new standard. This cautionary advice is particularly important when one recognizes that the Department of Labor's legal test for determining employment status is much less rigorous than the standard applied by the Internal Revenue Service.

Identity of Source Individual Another unresolved issue arises in the context of a healthcare facility's obligations to exposed workers. The standard requires employer disclosure of the identity of the source individual involved in the exposure incident. Healthcare employers are exempted from this element of the standard where identification is prohibited by state or local law. However, this continues to be a developing area of the law, with much variation among the states, and many employers may find unclear the jurisdiction's requirements on this issue.

Even where state and local law set forth special guidance on this issue, the legal rules may change over time. Employers therefore should consider incorporating a statement of their jurisdictions' respective disclosure laws in the employee policy manuals and periodically reviewing local law for any material changes.

Moreover, this element of the standard exempts an employer from the identification and disclosure provision where identification of the

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source individual is "infeasible." Although the text of the regulations does not expressly state the circumstances qualifying for the infeasible exemption, the standard's preamble, where OSHA discusses the authority and rationale underlying this new standard, provides some insight. The preamble indicates that exposure incidents involving unmarked or mislabeled sharps or blood samples may

qualify for the infeasible exemption. However, employers should clearly document the reasons for any determination of infeasibility.

SATISFYING OSHA OBLIGATIONS

OSHA's bloodborne pathogen standard, the agency's first major standard to protect healthcare workers, was initiated with substantial labor support and, as with other major OSHA rule making in recent years, is likely to become an enforcement target. This may be especially true this election year. Moreover, because many of the standard's requirements are objective, the Department of Labor may easily audit them. For example, an employer with no exposure control plan or vaccination or other required medical records is certain to draw citations and substantial penalties.

The OSHA bloodborne pathogen standard is highly technical and complex and, as a result, has understandably engendered much uncertainty and confusion regarding compliance. Healthcare facilities are encouraged to first thoroughly assess their workers' general exposure risks and to then assess all workers' specific duties to determine which job functions in fact involve a risk of occupational exposure. Under the standard, such jobs include all those where it is "reasonable to anticipate that contact with bloodborne fluids may result." With that knowledge, healthcare facilities can best satisfy their obligations under the new standard. □

This article is not intended as legal advice, which often may turn on specific facts. Readers should seek specific legal advice before acting with respect to this matter.